



TracMan

Tracheostomy Management in critical care

Full Protocol

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1 Overview of the TracMan trial

1.1 Introduction

This protocol describes a multicentre, randomised controlled trial (RCT) to determine whether “early” or “late” tracheostomy placement in critically ill adult patients requiring ventilatory support influences hospital mortality. The patients studied will be those expected to require further ventilatory support for 7 days or more when assessed on days 1 to 4 after admission to an intensive care unit. The setting will be adult Intensive Care Units (ICUs) within the National Health Service and private sector in the UK with the ability to provide Level 3 care as defined by “Comprehensive Critical Care”¹.

The TracMan trial is a pragmatic, effectiveness study, where the timing of the tracheostomy is determined randomly, but all other treatment decisions are left to the clinicians managing the patient. The nature of the intervention precludes blinding.

1.2 The need for an ‘early’ versus ‘late’ tracheostomy trial

There is inadequate evidence from large-scale randomised controlled trials to determine reliably the optimum time to perform a tracheostomy in ventilator-dependent patients. A detailed literature search located only two methodologically sound RCTs in this area, though both were small and single centre. One study showed a mortality benefit from early placement of a tracheostomy in patients on a medical ICU. The other showed no benefit in patients with cutaneous burns.

In spite of the lack of good evidence supporting either the use of tracheostomy or informing the correct time to perform one, large numbers of these procedures are carried out in the UK each year. The critical care community in the UK recently identified the timing of tracheostomy as an area of clinical equipoise, where good quality information from clinical trials was needed to inform practice. An expert panel viewed such a trial as both important and feasible.

A window of opportunity exists to carry out such a trial. A large, pragmatic, study of pulmonary artery catheters (PAC-Man) has just been completed. This was the first large scale, multicentre, non-commercial RCT in UK ICUs. The experience and goodwill gained during the PAC-Man study can be used to inform and establish another RCT. Tracheostomy management is also currently a topic of considerable interest internationally.

2 Existing state of knowledge

2.1 A brief history of studies involving tracheostomies

2.1.1 History of the procedure

The earliest records of tracheal cannulation date back to 2000-1000BC^{2,3}, but the first modern description of the surgical formation of a tracheal stoma (tracheostomy) is usually attributed to Dr Chevalier Jackson in 1909⁴. At the time, a tracheostomy was usually performed to relieve upper airway obstruction caused by diphtheria or laryngeal tumours.

A major development in the modern use of tracheostomies occurred in the early 1950s. In the 1930s and 1940s acute respiratory failure due to poliomyelitis was treated with external negative pressure ventilation (“iron lungs”). Whilst the artificial ventilation was initially life saving, many patients with bulbar palsy and impaired airway reflexes subsequently died from aspiration pneumonitis and pneumonia. In 1952 a severe poliomyelitis epidemic occurred in Copenhagen, but unusually many of the patients were treated with positive pressure ventilation delivered via a tracheostomy. The combination of airway protection and positive pressure artificial ventilation virtually halved the mortality from poliomyelitis⁵. Subsequently the use of a tracheostomy in other conditions requiring long-term (days to weeks) artificial ventilation became more common, though the point in a patient’s illness at which the advantages of a tracheostomy outweighed the risks of inserting one remained a source of considerable debate.

This longstanding uncertainty eventually led to an American consensus conference on artificial airways in patients receiving mechanical ventilation. The report from this conference was published in 1989⁶. The report recommended placement of a tracheostomy in patients on mechanical ventilation between days 10 and 21, or as early as possible if a requirement for long-term ventilation was identified prior to 10 days. No data were used to arrive at these recommendations, as no clinical trials had been performed to inform the discussions. The conference recommended that trials to compare tracheostomy with long-term translaryngeal ventilation, and trials of different timings for tracheostomy, should be undertaken. In the fifteen years since these recommendations were published, only two scientifically rigorous trials have been undertaken.

Traditionally tracheostomies were performed using an open, surgical technique, either in an operating theatre or at the bedside. The first report of a percutaneous tracheostomy technique appeared in 1957⁷, but the percutaneous dilatational technique in common use today dates from 1985 when Ciaglia and colleagues⁸ described the procedure and emphasised its rapidity, simplicity and safety. The technique could be used at the bedside, and did not require formal surgical training or surgical equipment. This gradually led to an increased and earlier use of tracheostomies in critically ill patients. A range of percutaneous tracheostomy techniques have now been described.

2.1.2 Clinical trials involving tracheostomies

Many trials have been performed comparing the outcomes of Ciaglia and other percutaneous techniques with surgical tracheostomy techniques, and meta-analyses of the

results of these trials^{9,10} broadly show that percutaneous and surgical techniques carry equal risks. Surprisingly, although both techniques have approximately equivalent risk, to date there is a paucity of data on whether *either* technique results in a direct benefit to the patient that would outweigh these risks. In spite of this uncertainty, tracheostomy is a frequent procedure in most ICUs in the UK, and is probably becoming increasingly common.

Although an obvious trial design would be to compare the use of a tracheostomy with the use of translaryngeal intubation (no tracheostomy) in artificially ventilated patients, this is not a practical option. Nearly all ICU clinicians would concur with the 1989 Consensus Conference view that patients requiring long-term ventilatory support (weeks or more) are better managed using a tracheostomy. This is because tracheostomies are perceived to facilitate nursing care (especially airway suctioning and mouth care), increase patient mobility by providing a secure airway, improve patient comfort, facilitate oral nourishment, reduce the requirement for sedation and allow limited speech. Although these benefits are mostly related to ease of care and comfort rather than survival, in patients requiring long-term ventilatory support these advantages outweigh the risks associated with the procedure to form the tracheostomy. It would be very difficult to find clinicians with sufficient equipoise to undertake a study that prohibited tracheostomy absolutely in one arm of the trial. A trial in France comparing tracheostomy with long-term translaryngeal intubation is currently underway (Blot and colleagues) but recruitment is proving difficult. These difficulties probably relate to clinicians' concerns about entering patients into a trial that limits tracheostomy in long-term ventilated patients.

The other reason not to undertake a tracheostomy/no tracheostomy trial is that the limited evidence available to date suggests there may be a benefit from *earlier* (and hence increased) use of tracheostomy compared with current practice. The consensus conference in 1989 recommended that tracheostomies should be placed in patients who still require artificial ventilation 10 days after admission to an ICU. There still appears to be a general compliance with this recommendation. Both the literature review undertaken to inform this protocol design and data from a detailed audit of Scottish ICUs (see page 10) suggest that on average tracheostomies are placed on day 10-11 of ventilatory support. However, there are now some limited data to suggest that earlier placement of tracheostomy might improve outcome in critically ill patients. The two most recent trials, and the only two that are methodologically sound^{11,12}, provided conflicting results. In patients with burns Saffle and colleagues showed no advantage to early tracheostomy, whilst Rumbak and colleagues halved the mortality rate and markedly reduced the ICU length of stay in patients in a medical ICU with early tracheostomy. Although the latter supports the use of early tracheostomy, it was a small, US, single centre study involving only medical patients, predominantly with acute or chronic respiratory conditions. The results may not be generalisable to the UK ICU population.

2.1.3 Mechanisms by which an early tracheostomy might benefit patients

The mechanism by which an early tracheostomy might improve mortality must be indirect. There is no known specific risk directly associated with medium-term translaryngeal intubation that can lead to death that would be avoided using a tracheostomy. However, tracheostomies are much better tolerated by patients because, unlike translaryngeal airways, they do not irritate the posterior pharyngeal wall and initiate a gag reflex. As a result patients with tracheostomies require far less sedation than patients with

translaryngeal airways, and in many cases require no sedatives at all. This may be why early tracheostomies alter patient outcome, as techniques to reduce sedative doses are known to alter ICU length of stay¹³. To date there are no studies of sedation with sufficient power to detect a change in mortality. There are also more subtle benefits to reduced sedative use, including reduced psychological morbidity in survivors¹⁴.

Another mechanism by which early tracheostomy might reduce mortality is by reducing the rate of nosocomial pneumonia in ventilated patients (ventilator associated pneumonia or VAP). The agonal event in many patients who die in ICUs is a nosocomial infection, and this is frequently a pneumonia. Data from the Rumbak study shows a reduced rate of nosocomial pneumonias in the early tracheostomy arm¹¹.

2.1.4 Summary of history

In summary, tracheostomy is a common procedure but with a limited evidence base to support its use. There are only two methodologically sound randomised controlled trials, and only one of these is in a mixed ICU population¹¹. These results may not be generalisable to patients in UK ICUs, but showed that early tracheostomy markedly reduced mortality. We wish to determine if the results of this single centre American trial which recruited only acute medical patients can be duplicated in a multicentre trial in UK ICUs.

2.2 Background to the TracMan trial

In the latter months of 2003, the Intensive Care Society (ICS) carried out a research priority-setting exercise among its UK membership of over 2,200 critical care staff. The exercise involved two rounds of questionnaires. The initial questionnaire asked individuals to suggest areas of research that would answer clinically important questions and might lead directly to improved patient outcomes. The second round questionnaire listed the seventeen topics most frequently suggested in the first round, and asked individuals to score the importance of each one (details on www.ics.ac.uk, under 'Latest News' section, 'Director of Research Update'). Each of the seventeen topics and its ranking from the second round was then reviewed by an expert panel of researchers and clinicians to assess the feasibility of undertaking a multicentre randomised clinical trial in that area. The research topic that was highly ranked by both the ICS membership and the expert panel was:

Does "early" tracheostomy (compared with "late" tracheostomy) alter the outcome of patients requiring ventilatory support?

The ICS decided to undertake a randomised controlled trial in this area.

2.3 Determining the current evidence informing the use of tracheostomy

Given the long history of tracheostomies it was important to ensure adequate studies had not already been performed on the use of tracheostomy prior to undertaking a trial. For this reason a systematic review of the literature was undertaken before this protocol was prepared.

2.3.1 Identification of published randomised controlled trials (RCTs)

A literature review was undertaken to identify any randomised controlled clinical trials comparing either tracheostomy with continuing translaryngeal intubation, or comparing different timings for tracheostomy. A systematic literature search was carried out in early 2004 to identify published and ongoing studies relating to tracheostomy in critical care patients. Electronic searching of Medline (initially 1993 to January 2004 and subsequently the full database from 1976), the Cochrane Library, the National Research Register, the NHS Trusts Clinical Trials Register, the Medical Research Council UK database, the NHS Research and Development Health Technology Assessment Programme, and the British Heart Foundation database was performed. The search strategies for Medline were based on the terms recommended by the Cochrane Collaboration to identify randomised controlled trials coupled with terms to identify tracheostomies.

Relevant studies were initially identified by title, and then by abstract and finally by full text. Snowballing was also performed from the reference lists of identified reports of randomised controlled trials and systematic reviews.

No randomised controlled trials comparing tracheostomy with continuing translaryngeal intubation were located. Six studies comparing different timings for tracheostomy were identified, spanning the period 1976-2002 (Appendix 1). Two systematic reviews of early versus late tracheostomy were identified^{15,16}, but these contained no information beyond that reported in the primary reports of the trials.

All of these studies were undertaken in the United States. Only two of the studies used appropriate randomisation^{12,17}, and only one paper contained sufficient data to determine the allocation and outcome of all the patients¹². In this trial Saffle and colleagues studied 44 patients with acute cutaneous burns who were still intubated on day 2 following admission, and who had a predicted duration of ventilation of 14 days or more calculated using a previously validated model. The “early” tracheostomy arm received a tracheostomy as soon as possible after randomisation. The “late” arm received a tracheostomy on or after day 14. The “early” arm hospital mortality was 19 per cent, the “late” arm mortality was 26 per cent, which was not statistically different. The hospital lengths of stay were equivalent. The other two studies that reported hospital mortality^{17,18} also showed similar hospital mortality in patients receiving early and late tracheostomy.

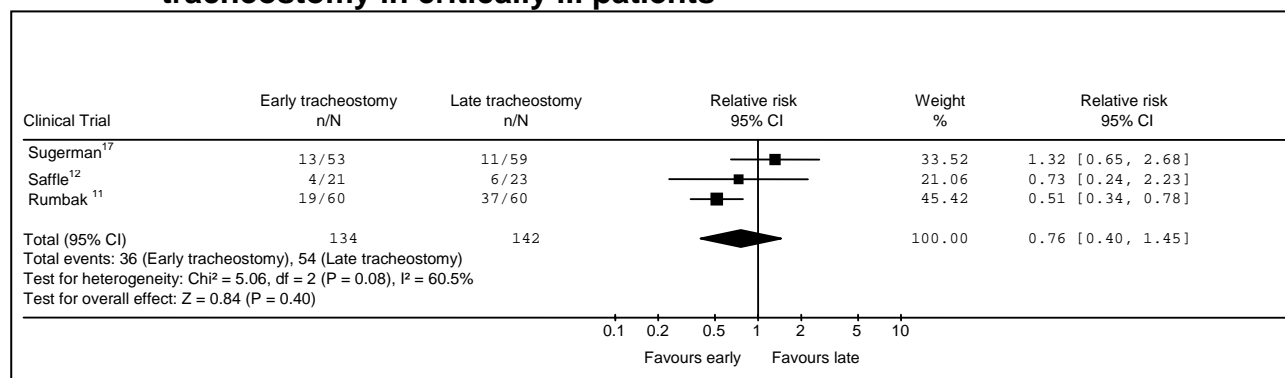
The largest and most methodologically sound study of “early” and “late” tracheostomy has been completed, but is as yet unpublished. The authors kindly supplied a copy of their final manuscript, which has been accepted for publication and therefore has undergone peer review. Rumbak and colleagues¹¹ randomly assigned 120 patients in a medical ICU with a predicted period of ventilation of 14 days or more to either “early” tracheostomy (within 2 days) or “late” tracheostomy (14 days or greater). The “early” tracheostomy arm experienced a much lower 30 day mortality (32 against 62 per cent, $p < 0.005$), and a lower incidence of pneumonia, a shorter duration of ventilation and a shorter stay in intensive care. This study recruited only medical (non-surgical) patients of whom half were being treated for exacerbations of chronic obstructive lung disease.

Additionally, six retrospective reviews/prospective unrandomised observational studies^{19,20,21,22,23,24} were identified relating to the timing of tracheostomy in critical care patients (Appendix 2). In general they show no difference in mortality between the early and late groups, but longer lengths of stay in the late groups. Given the non-randomised

nature of the studies, and the differing definitions of early and late tracheostomy, no useful conclusions can be drawn from them.

We undertook a meta-analysis of the three methodologically sound trials of tracheostomy timing^{11,12,17} to obtain an estimate of the likely treatment effect. The forest plot is detailed below. The relative risk reduction using a random effects model was 24% (95% CI – 60% to + 45%).

Figure 1: Forest plot showing methodologically sound trials of timing of tracheostomy in critically ill patients



March 2006: For updated evidence see section 3.20 of this protocol (page 18).

2.3.2 Identification of data to inform the protocol development and power calculations

The literature on randomised trials did not provide sufficient data on event rates on which to base power calculations. For this reason a repeat search of Medline excluding the requirement for randomised controlled trials was undertaken to find case series containing these data.

A total of 110 studies were identified (Appendix 3). Data were extracted to determine the timing of tracheostomy after ICU treatment or artificial ventilation started, the hospital mortality and the ICU length of stay. Hospital length of stay was so rarely reported that no useful data could be generated. A total of 14,962 patients received tracheostomies in the studies. Fifty-seven studies reported the timing of tracheostomy, the unweighted mean was slightly over 10 days following initiation of artificial ventilation. Fifty-one studies reported hospital mortality which averaged 38 per cent (unweighted) in the tracheostomised patients. Sixteen studies reported ICU length of stay which averaged 20 days (unweighted).

2.3.3 Survey of UK hospitals

To try to obtain up-to-date information on the use of tracheostomies in UK ICUs we conducted a targeted survey. In February 2004 the individuals who had scored any type of tracheostomy-related research highly in the priority-setting exercise were contacted. The most recent information on the number of tracheostomies performed in their ICU, the mortality rate for tracheostomised patients and the overall admission rate was requested. If the data were not available an estimate was requested. We received replies from 41 ICUs.

Thirty-five of the ICUs provided accurate (not estimated) figures therefore the six estimated values were not used. All the data supplied were for periods of six months or a year ending between 31/12/2003 and 12/02/2004. The average number of tracheostomies per year per ICU was 65, representing tracheostomy placement in 16 per cent of all ICU admissions. On average 21 per cent of these patients died before leaving ICU. The questionnaire used and the full table of results are shown in Appendix 4.

2.3.4 Data from the Scottish Intensive Care Society Audit Group (SICSAG)

All adult ICUs in Scotland participate in a national audit program. Data from 1999-2000 on tracheostomy use in Scotland were reported in the SICSAG 2002 annual report (http://www.scottishintensivecare.org.uk/sicsag_index.htm). About eight per cent of all ICU admissions in Scotland during this time received a tracheostomy, the median time for insertion was day 10-11 following ICU admission. There was a large variation in practice, the median day for tracheostomy insertion varied between 6 and 16 days across individual Scottish units. There was a suggestion that the proportion of patients receiving a tracheostomy is increasing.

2.3.5 Identification of other protocols

We also located one published protocol for a study of the use of tracheostomy compared with continuing translaryngeal intubation²⁵. The study detailed in this protocol is currently underway and has recruited approximately 100 patients (April 2004). The principal investigator kindly supplied copies of the full protocol and trial documentation, and an update on trial progress. This trial may close before reaching its target sample size, because of slow recruitment. As mentioned in section 2.1.2, this may be because of a reluctance to recruit to a trial where tracheostomy use is severely limited in very long stay patients.

The Scottish Intensive Care Society supplied a draft, unpublished protocol of a proposed study to look at the timing of tracheostomy, and has elected to assist with this trial rather than proceeding with a study of its own.

3 The TracMan trial

3.1 Trial design

TracMan is a pragmatic, multicentre, prospective, open, randomised controlled trial.

3.2 The hypothesis

In patients predicted to require ventilatory support for 7 days or more, placing a tracheostomy on day 1 to 4 following ICU admission reduces mortality at day 30 (post randomisation) compared with a tracheostomy placed on or after day 10.

3.3 The intervention

This trial is not introducing a new procedure but will be evaluating the *timing* of tracheostomy. Specifically:

“Early” tracheostomy:
Tracheostomy to be performed on day 1-4 post admission to ICU

Compared with

“Late” tracheostomy:
No tracheostomy before day 10 post admission to ICU

There is no “usual treatment” arm *per se* as we identified a wide spread of tracheostomy timings in the literature and in the SICSAG audit data. However both of these sources of data suggested that tracheostomies are most commonly placed on day 10-11 following ICU admission. Therefore the timing of tracheostomy placement in the “late” tracheostomy group has been set at day 10 or later to reflect average “usual treatment”.

There will be a number of patients in whom either a tracheostomy will not be required on day 10, either because ventilatory support is no longer needed or the clinicians are reasonably certain that the patient will only need ventilatory support for a further brief period.

3.4 Outcome measures

Primary outcome measure: Mortality 30 days after randomisation.

Secondary outcome measures: Mortality rate at discharge from hospital
ICU length of stay
Hospital length of stay
Mortality rate at (first) discharge from ICU
Number of days receiving sedative medication
Number of antibiotic-free days.

3.5 The setting

Adult, ICUs in the NHS and private sector in the United Kingdom able to care for Level 3 patients as defined by “Comprehensive Critical Care”¹.

3.6 The target population

All adult intensive care patients requiring artificial ventilation who meet the inclusion criteria.

3.7 Patient eligibility

Only patients being considered for a tracheostomy should be included in the study.

On days 1 to 4 following ICU admission, the primary caring ICU clinician should determine whether there is a high chance that patients with type 1 or type 2 respiratory failure (of any cause) will require a further 7 days or more of ventilatory support during their ICU stay.

3.7.1 Inclusion criteria:

A patient may be deemed suitable for the study according to the uncertainty principle. If the clinician responsible for the patient’s care and the patient (or their representative) are uncertain about whether an “early” or “late” tracheostomy is more appropriate, the patient is eligible for inclusion in the trial (subject to the usual informed consent procedures).

3.7.2 Exclusion criteria:

The uncertainty principle can also be used to determine which patients are ineligible for the trial. However ethical approval requires explicit listing of excluded patients and vulnerable groups. The following patients must not be included in the trial:

Patients:

- not assessed on days 1-4 following ICU admission regarding their predicted requirement for at least a further 7 days of ventilatory support.
- for whom an immediate tracheostomy is required to alleviate upper airway obstruction.
- with a tracheal stoma or tracheostomy tube in situ on admission to the ICU.
- with chronic hypercarbic (type 2) respiratory failure due to a chronic neurological disease.
- less than 16 years of age.
- previously enrolled in the TracMan trial during the same hospital admission.
- for whom consent was refused.
- or their relative/legal representative who does not understand written or verbal information for whom an interpreter is not available.
- transferred to your ICU from another ICU.

3.8 When to consider a patient for the trial

On days 1 to 4 following ICU admission, the primary caring ICU clinician should determine whether there is a high chance that patients with type 1 or type 2 respiratory failure, will require a further 7 days or more of ventilatory support during their ICU stay.

We recognise that this is a subjective trial entry criterion. Scoring systems and predictive indices for the duration of mechanical ventilation have been developed for both general ICU patients and specific subgroups (for example^{26,27,28}), but we have elected to use the clinicians' estimate of future ventilatory requirements as the entry criterion. This is because both the Rumbak¹¹ trial and the trial currently underway in France²⁵ use this method, and so comparability is enhanced. In addition, many of the published scoring systems require considerable data collection, simply codify clinical knowledge, or have not been validated on a test population. Finally, in clinical practice the decision to place a tracheostomy is based on a clinician's estimate of the patient's requirement for ongoing ventilation rather than a scoring system.

3.9 Formal trial entry and random allocation

Allocation to a treatment arm will be made randomly. A central specialist telephone randomisation service will be used.

Randomisation will occur once a patient meets the inclusion criteria and has consented to the trial. When a clinician contacts the randomisation service, basic descriptive information will be requested. Once these details have been supplied, the random allocation will be given in return. The allocation will be minimised according to the patient's age and sex, broad diagnostic category, and the recruiting ICU.

The nature of the intervention means that blinding of allocation is impossible.

A member of the TracMan team will be available 24-hours a day, 7 days a week, to address any emergency recruitment issues. The contact details for this person will be available from the randomisation service.

3.10 Patient consent

Wherever possible informed consent will be obtained from patients prior to randomisation (Appendix 5). It is recognised that in the majority of cases the patients will be unable to give informed consent due to alterations in conscious level caused by illness and therapeutic sedation. In these cases consent will be obtained in line with the legal requirements for each country (see Appendices 6-8)

3.11 Clinical management of the 'early' tracheostomy arm

Patients allocated to this arm will have either a percutaneous or surgical tracheostomy at any time during day 1 to day 4 following ICU admission. The technique for tracheostomy will be determined by local practice and will be recorded. Immediate adverse events will be recorded.

3.12 Clinical management of the 'late' tracheostomy arm

Patients allocated to this arm should not have a tracheostomy before day 10 following ICU admission.

The clinician responsible for their care will review their need for a tracheostomy at day 10, when either of the following strategies may be followed:

- (a) a percutaneous or surgical tracheostomy is performed on or after day 10

or

- (b) no tracheostomy is carried out as it is no longer appropriate to do so (or the patient is no longer in ICU).

3.13 Tracheostomy procedure type

The trial will enrol centres where percutaneous and/or surgical tracheostomies are carried out, according to local current standard practice. The responsible ICU consultant will make all non-protocol management decisions, including the selection of the appropriate procedure for tracheostomy. The mode of ventilation and weaning from ventilatory support will not be protocolised.

3.14 Proposed duration of treatment

A tracheostomy will stay in-situ until decannulation is considered clinically appropriate by the primary caring team.

3.15 Risks associated with the trial

The trial is evaluating the best *time* to perform a tracheostomy. The possible risks related to the timing of tracheostomy are essentially represented by the outcome measures of the trial as no hard evidence is available. The risks related to the tracheostomy procedure itself are the same whether the patient takes part in the trial or has a tracheostomy outside of the trial.

3.16 Adverse Events

As tracheostomy is standard practice in the ICU there are no anticipated complications of tracheostomy associated with the TracMan trial itself. Nevertheless the local research team shall record all complications on the appropriate Case Report Form. The Principal Investigator will report any serious, unanticipated adverse events occurring during the investigation to Dr J D Young within 3 working days: Dr Duncan Young, TracMan Trial Office, Kadoorie Centre for Critical Care Research and Education, John Radcliffe Hospital, Oxford OX3 9DU. Tel: 01865 857652, Email: TracMan@nda.ox.ac.uk.

3.17 Patients not in the trial

Brief details of patients assessed on Day 1-4 but not in the trial will be recorded on a Patient Screening Log (Appendix 11), at each collaborating unit. Recording this information is to establish an unbiased case selection and full reporting according to the CONSORT statement^{29, 30}.

3.18 Data collection

Clinical data will be collected in a standardised way on a trial specific data form as detailed overleaf. Copies will be retained at the recruiting centre. Data will be transcribed from the patient's notes or the clinical information system (CIS) by the team responsible for the patients' care.

Units collaborating in TracMan and also participating in the Intensive Care National Audit and Research Centre (ICNARC) Case Mix Programme (CMP) will only be required to complete part of the dataset requested on the TracMan trial datasheet. This is because common data (eg admission APACHE II score, hospital mortality etc) are collected by the CMP and the sharing of such data will reduce the data collection burden for collaborating units and avoiding repetition.

Once the TracMan trial datasheet arrives in the trial office in Oxford, the unique CMP identifier recorded will enable the trial office to request appropriate data from the CMP in London. The TracMan trial statistician is based at ICNARC where the CMP data is based. The data will be transferred electronically to Oxford, or will be personally handed over on disc (encrypted).

We predict over half the ICUs recruited to the trial will be participants in the CMP. ICNARC will obtain signed agreement in advance from collaborating units to share this anonymised data with TracMan. This approach has been used in the PAC-Man trial and works well.

The CMP database has extensive data validation checks in place.

Before the study starts, data collection forms will be piloted to determine ease of use, inter-rater variability and other practical issues by collecting data on patients routinely treated with and without tracheostomies on the Adult ICU at Oxford and one other test site.

Data are collected for the period of the patient's stay in ICU. The hospital discharge date will be obtained from the local patient administration system. When a patient is transferred to another acute hospital, the discharge date will be requested from the receiving hospital. However for some patients it may be necessary to contact the patient's general practitioner to obtain the patients status.

Patients will be 'flagged' on the Office of National Statistics (ONS) database to ensure reliable collection of the primary outcome measure (patient status 30 days after randomisation). Patients alive at day 30 will be followed up for two years on the ONS database.

3.19 Sample size

The planned sample size is 1692 patients (846 in each arm).

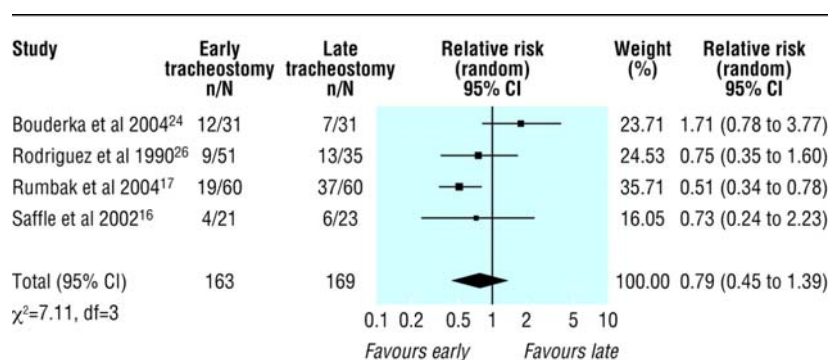
3.20 Justification for sample size and details of the power calculation

The sample size calculations are based on the primary outcome measure, 30 day mortality. There are no data available in the UK on 30 day mortality in critically ill patients receiving tracheostomies so we used hospital mortality as a surrogate for 30 day mortality. There are a number of estimates of hospital mortality in tracheostomised patients on which to base the calculations.

The survey of 35 UK ICUs gave a mean value of 21 per cent for ICU mortality for tracheostomised patients. Hospital mortality is invariably higher than ICU mortality³¹, the mean increase in mortality between ICU and hospital discharge in the UK is 9.3 per cent absolute. Thus the predicted hospital mortality for these tracheostomised patients would be slightly over 30 per cent. This is very close to the UK average hospital mortality for all ICU admissions of 30.8 per cent³¹.

A meta-analysis carried out in 2005 of four methodologically sound published trials of tracheostomy timing show a relative risk reduction of 21 per cent.

Figure 2: Forest plot showing random effects meta-analysis of relative risk (95% confidence interval) of mortality with early compared with late tracheostomy.



Griffiths J, Barber VS, Morgan L, Young JD. Systematic Review and meta-analysis of studies of the timing of tracheostomy in adult patients undergoing artificial ventilation. *BMJ* 2005;330:1243-47.

We therefore selected a 21 per cent relative reduction in mortality as the clinically significant difference we wished our trial to detect.

Using a difference in hospital mortality of 21 per cent relative, 6.3 per cent absolute, with a predicted mortality in the “late” arm of 30 per cent, with an 80 per cent certainty of detecting a real difference and an alpha value of 0.05 the calculated sample size with a continuity correction is 1616 patients (808 in each arm).

In a recently completed multicentre study of pulmonary artery catheters in ICU patients (PAC-Man), 2.4 per cent of recruited patients or their relatives subsequently withdrew their consent, or were randomised in error. A similar dropout rate in this study would require a total of 828 patients per arm (1656 total). In addition there will be a cross-over rate, again using PAC-Man data we estimate this to be 2 per cent in the late arm. This gives a required sample size of 846 patients per arm (1692 total). This value has been chosen as the sample size for the trial.

We have reviewed the effects that differing estimates of hospital mortality might have on the power of the study. The absolute difference detectable at the same power is slightly higher (i.e. the trial would be less sensitive) if the true mortality in the late arm exceeds that predicted, but would be lower if the true late mortality is less than that predicted. Table 1 below summarises the effects of differing estimates of hospital mortality would have on the power of the study assuming the same sample size and levels of certainty.

A study size of 1692 patients will allow a difference of less than one day in the secondary outcomes of length of ICU and hospital stay to be detected. Data are not available to estimate the power to detect changes in antibiotic use and sedative use.

Table 1: Hospital mortality estimates

Source of estimate	Hospital mortality (%)	Relative mortality reduction detectable	Absolute mortality reduction detectable
Lowest value from survey of UK ICUs	9%	42.2%	3.8%
Highest value from survey of UK ICUs	58%	12.2%	7.1%
Literature review	38.1%	17.8%	6.8%
SICS audit	8%	43.8%	3.5%

Should the TracMan trial obtain further funding, it could be extended to both increase the certainty of detecting a 21 per cent relative reduction in mortality, and increase the chances of detecting a lesser treatment effect. Table 2 below gives the sample size required to detect a 21 per cent relative reduction in mortality from a control group mortality of 30 per cent for a power of 90 per cent, 95 per cent, and 99 per cent.

Table 2: Sample size calculations

Power	Total sample size with continuity correction	Sample size allowing for crossovers and dropouts
80%	1616	1692
90%	2140	2284
95%	2630	2806
99%	3690	3938

3.21 Planned recruitment rate

To ensure generalisability of the results we plan to recruit a minimum of 30 ICUs to take part in the study. From the results of the UK survey we expect these units will average 450 admissions/year with a predicted mean rate of tracheostomy of 16 per cent. With 30 ICUs this gives a potential pool of 2160 patients per year to recruit to the trial. If an estimated 30 per cent of these patients are unsuitable for recruitment to the trial, the pool of potential recruits decreases to 1512. Allowing for time to initiate and train each ICU, and time to collect the hospital mortality data at the end of the study, the recruitment phase of the study should take between 18 months and 2 years.

An alternative estimate has been derived from the North Thames ICU database of 53,135 ICU admissions. In this database 10.6 per cent of admissions remained in the ICU for 10 days or more. The long-stay patients had a tracheostomy rate of 42 per cent. Using the same estimates of unit numbers and ICU admissions above a potential pool of 601 patients per year would be available to recruit to the trial. Using the assumptions above this would give a trial duration of between 3 and 3¹/₂ years.

3.22 Type of analysis

The principal comparisons will be between those allocated to “early” tracheostomy and those allocated to “late” tracheostomy (the “intention to treat” principle). The primary outcome variable will be proportion of patients surviving to 30 days post randomisation in each arm which will be compared using Fisher’s exact test.

Hospital and ICU mortality will also be compared between arms using Fisher’s exact test. The survival curves for the two arms will be calculated using the Kaplan-Meier method, with the starting time being the time of randomisation, and compared using a log-rank test. Differences in length of ICU stay, hospital stay, number of days sedated and number of antibiotic-free days between arms will be tested using the Wilcoxon rank-sum test.

Mr D. Harrison, Senior Statistician at ICNARC, will act as trial statistician and perform the analyses.

3.23 Subgroup and exploratory analyses

Additional analyses will explore:

- The effect of early tracheostomy on length of hospital stay, 30 day and hospital mortality in subgroups with different severity of illness determined by APACHE II scoring on ICU admission
- The effect of early tracheostomy on length of hospital stay, 30 day and hospital mortality in broad subgroups (intracranial pathology, respiratory infections etc.) with different causes of respiratory failure
- The effect of early tracheostomy on length of hospital stay, 30 day and hospital mortality in subgroups with different tracheostomy procedures (percutaneous or surgical), assuming sufficient patients in the “late” arm have a tracheostomy to allow this analysis.
- The effect of early tracheostomy on length of hospital stay, 30 day and hospital mortality in subgroups defined by the grade of the primary operator, assuming sufficient patients in the “late” arm have a tracheostomy to allow this analysis.
- The effect of early tracheostomy on length of hospital stay, 30 day and hospital mortality in subgroups of ICUs of varying sizes.
- Whether the duration of ventilatory support can be predicted using a model based on clinical and laboratory information available on days 1-4, and whether the subsequent use of tracheostomy adds explanatory power to the model.

3.24 Compliance and crossovers

The primary responsibility for the care of ventilated patients on ICUs passes from one consultant to the next on a daily or weekly basis depending on the type of duty roster. To ensure compliance with the trial protocol throughout a patient’s stay, and to avoid cross-over after allocation to either the “early” or “late” arm, only ICUs where *all* the consultants agree to abide by the protocol will be used as recruiting centres.

3.25 Frequency and timing of analyses

The frequency and timing of analyses will be determined by the Data Monitoring and Ethics Committee (DMEC) in line with its Standard Operating Procedures (see page 23).

3.26 Economic analysis

Currently there is no funding available for an economic analysis. The steering group will investigate strategies to fund an economic analysis.

3.27 Will there be NHS cost implications as a result of this trial?

The patient will not require any special tests or extra hospital visits over and above standard care.

Materials required for data collection will be supplied by the TracMan Trial Office. The data collection burden will be kept to the minimum compatible with a scientifically valid result from the trial. The main NHS cost will be an opportunity cost incurred by in-post personnel seeking consent and collecting the data, which we expect to amount to 1-2 hours/patient.

3.28 Ethics approval

New standard operating procedures for Research Ethics Committees (RECs) came into force from 1st March 2004, more details are available from <http://www.corec.org.uk/PDF/Guidance%20for%20Applicants%20to%20RECs.pdf>.

Under these new rules the ethics application made by the Chief Investigator (Duncan Young), once approved, will cover all collaborating sites. However, whilst this is the only ethical review of the trial required as part of the new procedures, it is necessary for collaborating Sites to have a Site Specific Assessment (SSA) carried out locally before the trial can begin in their hospital(s).

Under the new rules a “Sponsor” is required for the trial. The Oxford Radcliffe Hospitals NHS Trust will assume this role.

3.28.1 Site Specific Assessments

The Principal Investigator at each Trust will be notified by the Trial Office when it is time to apply for a Site Specific Assessment (SSA). A SSA is not an *ethical* review, but a process of confirming that there are no objections to the trial on site-specific grounds. Further details will be forthcoming from the Trial Office at the appropriate time, as the details of the new system become clearer.

3.29 The EU Directive for Clinical Trials of Medicines in Human Subjects

The EU Clinical Trials Directive (Directive 2001/20/EC) (<http://www.ncchta.org/eudirective/index.asp>), came into force on 1st May 2004. As this trial does **not** involve a “medicinal product” it is not required to comply with the Directive.

This trial will be managed according to the Medical Research Council’s Guidelines for Good Clinical Practice in Clinical Trials (<http://www.mrc.ac.uk/pdf-ctg.pdf>).

3.30 Trial funding

The Intensive Care Society funded the trial 2004 to end March 2006. The Medical Research Council funded the trial from 1st April 2006. Funding covers the trial office staff who facilitate the trial. There is no direct financial support for collaborating ICUs. Many Trusts have a Research and Development office that may be able to help locate funding.

3.31 Publication of results

The success of the trial depends on the collaboration of consultants from across the UK. Equal credit will be given to those who have wholeheartedly collaborated in the trial.

The results of the trial will be reported first to trial collaborators. The main report will be drafted by the trial office team, and the final version will be agreed by the Steering Committee before submission for publication, on behalf of the collaboration.

Due to limited resources, it will be not be possible to provide each surviving patient with a personal copy of the results of the trial. Instead, with due regard to copyright issues relating to the publication of the results in peer reviewed journals, the trial results will be published on the ICS web site (<http://www.ics.ac.uk/>), where any member of the public may view the results. The ICS web site address will be provided on the patient information sheet.

3.32 Recruitment of ICUs

Identification of potential collaborators is currently ongoing. We always welcome new collaborators, if you are interested please contact Vicki Barber in the Trial Office on 01865 857652.

3.33 The Steering Committee

The trial is guided by a group of respected and experienced critical care personnel and trialists as well as a 'lay' representative. Face to face meetings will be held at regular intervals determined by need but not less than once a year. Routine business is conducted by email and post. Current membership of the Steering Committee is listed in Appendix 10.

3.33.1 Standard Operating Procedures for the Steering Committee:

The Steering Committee, in the development of this protocol and throughout the trial will take responsibility for:

- Major decisions such as a need to change the protocol for any reason
- Monitoring and supervising the progress of the trial
- Reviewing relevant information from other sources
- Considering recommendations from the DMEC
- Informing and advising on all aspects of the trial.

3.34 The Data Monitoring and Ethics Committee (DMEC)

3.34.1 Standard Operating Procedures for the DMEC:

- 1) During the period of recruitment into the study, interim analyses of the proportion of patients alive at 30 days and analyses of deaths from all causes at 30 days will be supplied, in strict confidence, to the chairman of the DMEC, along with any other analyses that the committee may request.
- 2) In the light of these analyses, the DMEC will advise the Chairman of the Steering Committee if, in their view, the randomised comparisons have provided both (i) 'proof beyond reasonable doubt' that for all, or some, the treatment is clearly indicated or clearly contra-indicated and (ii) evidence that might reasonably be expected to materially influence future patient management.

- 3) Appropriate criteria of proof beyond reasonable doubt cannot be specified precisely, but the DMEC will work on the principle that a difference of at least 3 standard deviations in an interim analysis of a major outcome event may be needed to justify halting, or modifying, a study before the planned completed recruitment. These criteria have the practical advantage that the exact number of interim analyses would be of little importance, and so no fixed schedule is proposed.
- 4) Following a report from the DMEC, the Steering Committee will decide whether to modify entry to the study (or seek extra data). Unless this happens the Steering Committee and the collaborators will remain ignorant of the interim results.
- 5) Data relating to the safety of patients will be reviewed by the Chair of the DMEC once 50 patients have been randomised to the trial. The data reviewed will specifically relate to:
 - a) procedure related 'serious, unanticipated adverse events' (death or serious disability)
 - b) procedure related adverse events/ complications
 - c) deaths at 30 days (any cause)
- 6) The DMEC will meet to review one year (Aug 05), or at 100 deaths, whichever occurs first. The DMEC will meet annually thereafter.

The DMEC comprises of a senior statistician, a senior clinician, and a senior trialist (Chair), see Appendix 11.

3.35 Central co-ordination

The trial is co-ordinated by the ICS Trials Group based at the Kadoorie Centre for Critical Care Research and Education at the John Radcliffe Hospital in Oxford. Administrative and academic support is supplied by the Nuffield Department of Anaesthetics, University of Oxford.

All day-to-day co-ordination of the trial will be the responsibility of Dr Vicki Barber. All clinical co-ordination of the trial will be the responsibility of Dr Duncan Young.

The trial office team (Appendix 12), will assist and facilitate the setting up of centres wishing to collaborate in the trial. In addition the trial office team will:

- Distribute the standardised data collection forms to collaborators
- Organise the telephone randomisation service for formal trial entry
- Monitor the collection of data, process data and seek missing data
- Ensure the confidentiality and security of all trial forms and data
- Conduct extensive data checking and cleaning
- Organise any interim and main analyses
- Organise Steering Committee, DMEC and Collaborators meetings

The trial office will receive completed data forms (anonymised), via the postal service. Upon receipt, data forms will be checked for completeness and entered into a trial-dedicated computer programme which will check the data validity. To ensure reliability, data will be entered twice by different members of the trial office team. The first and second entry data will then be compared to identify any potential data input error.

Patient confidentiality will be maintained at every stage and we comply with the Data Protection Act (1998).

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Literature search: Tracheostomy clinical trials

APPENDIX 1

Authors	Rumbak et al ¹¹	Saffle et al ¹²	Sugerman et al ¹⁷	Rodriguez et al ¹⁸	Dunham et al ³²	Stauffer et al ³³	El-Nagger et al ³⁴
Publication year	(In press, 2004)	2002	1997	1990	1984	1981	1976
Patient population	Patients in three medical ICUs with a predicted ventilation period of 14 days or greater, with an APACHE II score >25	Patients with acute cutaneous burns intubated on day 2 following admission, with a predicted duration of ventilation >= 14 days calculated using a previously validated model	Patients with trauma or respiratory failure in level 1 trauma centres intubated on day 3 following admission, with a predicted duration of ventilation or requirement for airway control >= 7 days	Patients with multiple injuries requiring ventilation > 1 day	Patients with multiple injuries ventilated for 3* days expected to require at least 2 days more ventilation	Medical and surgical ICU patients ventilated for two days expected to require prolonged use of an artificial airway	Patients with acute respiratory failure intubated for 3 days, expected to require prolonged ventilation
Setting	Three medical ICUs, USA	One burns unit, USA.	Five level 1 trauma centres, USA	One surgical intensive care unit, USA	One level 1 trauma centre, USA	Two hospitals, USA	One hospital, USA
Age limits	>18 years	>18 years	>18 years	Not stated	Not stated	Not stated	Not stated
Exclusions	Anatomical abnormality of the neck, abnormal coagulation, local infection, PEEP>12cmH2O	Pregnancy, hepatic or renal failure, corticosteroid treatment	Burns and inhalational injuries	Patients being actively weaned from ventilation	Not stated	Laryngeal or tracheal disease, previous tracheostomy or prolonged intubation, facial trauma or surgery, acute burns	Not stated
Total sample size	120	44	112	106	74	150	52
Randomised?	Yes	Yes	Yes	Quasi-randomised	Quasi-randomised	Quasi-randomised	Quasi-randomised
Method of randomisation	Randomly generated assignment contained in sequentially numbered envelopes	Randomly generated assignment contained in sequentially numbered envelopes	Randomly generated assignment contained in envelopes. Stratified into three groups (trauma and GCS <= 8, trauma and GCS > 8, respiratory failure) <i>Re-randomisation</i> at day 10-14 if in the late group	Assignment by date, odd days = "early" arm, even days = "late" arm	Assignment determined by the last digit of the patient's hospital number	Assignment determined by the last digit of the patient's hospital number	Sequentially divided into 2 arms
Early arm definition	Tracheostomy within 2 days of start of artificial ventilation	Tracheostomy placement during next available operating day (usually day 3)	Tracheostomy between day 3 and 5 after admission	Tracheostomy within 7 days of admission	Tracheostomy 3-4 days after initiation of ventilation	Tracheostomy 2 days after initiation of ventilation	Tracheostomy after day 3 of mechanical ventilation
Late arm definition	Tracheostomy >=14 days after initiation of artificial ventilation if still ventilated	Tracheostomy on post burns day 14 if still intubated	Tracheostomy on day 10-14 post admission if still intubated and major head injury. At which point possible to re-randomised to either (1) tracheostomy on day 10-14 or (2) tracheostomy later than day 21	Tracheostomy at least 8 days after admission	Tracheostomy >14 days after initiation of ventilation	Tracheostomy up to 21 days after initiation of ventilation	Tracheostomy >10 days after initiation of ventilation

Literature search – Tracheostomy clinical trials – Appendix 1 continued/...

Authors	Rumbak et al ¹¹	Saffle et al ¹²	Sugerman et al ¹⁷	Rodriguez et al ¹⁸	Dunham et al ³²	Stauffer et al ³³	El-Nagger et al ³⁴
Tracheostomy technique	Percutaneous	Surgical or percutaneous (in operating theatre)	Physician's choice, (73% percutaneous)	Not stated	Surgical	Not stated	Not stated
Early/late n	60/60	21/23	53/59	51/55	34/40	Not stated	26/26
ICU mortality early arm	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated
ICU mortality late arm	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated
Hospital mortality early arm	19 (32%)*	4 (19%)	13 (25%)	9* (18%)	Not stated	Not stated	Not stated
Hospital mortality late arm	37 (62%)*	6 (26%)	11 (19%)	13* (23%)	Not stated	Not stated	Not stated
ICU LOS early arm (days)	Mean 4.8 SD 1.4	Not stated	Mean 20 SD 2	Mean 16 SD 1	Not stated	Not stated	Not stated
ICU LOS late arm (days)	Mean 16.2 SD 3.8	Not stated	Mean 24 SD 2	Mean 37 SD 4	Not stated	Not stated	Not stated
Hospital LOS early arm (days)	Not stated	Mean 58.4 SD 6.3 Range 14-124	Not stated	Mean 34 SD 4	Not stated	Not stated	Not stated
Hospital LOS late arm (days)	Not stated	Mean 57.3 SD 8.0 Range 11-153	Not stated	Mean 51 SD 4	Not stated	Not stated	Not stated
Patients developing pneumonia, early arm	3 (5%)	21 (100%)	26 (49%)	25* (50%)	20 (59%)	Not stated	Not stated
Patients developing pneumonia, late arm	15 (25%)	22 (96%)	32 (57%)	47* (85%)	20 (50%)	Not stated	Not stated
Late arm patients receiving tracheostomy	Not stated	Not stated	Not stated	Not stated	20 (50%)	Not stated	10 (19%)
Other outcomes	Laryngeal trauma equal in arms	1/21 (4.8%) decannulated by 14 days in early arm, 7/23 (30%) decannulated by 14 days in late arm	None stated	None stated	None stated	None stated	None stated
Comments	* = 30 day mortality	Mortality assumed to be hospital mortality	Additional group recruited on day 10-14 post injury, not included in this summary. Mortality assumed to be hospital mortality.	* = Calculated values not reported in the original publication	* = Text is ambiguous, elsewhere ventilated > 7 days is given as an inclusion criterion.	No data on outcome by group in paper	No data on outcome by group in paper

Literature search: Tracheostomy retrospective chart reviews/prospective observational studies

APPENDIX 2

Authors	Teoh et al ¹⁹	Brook et al ²⁰	Armstrong et al ²⁴	Blot et al ²¹	D'Amelio et al ²²	Lesnik et al ²³
Publication year	2001	2000	1998	1995	1994	1992
Patient population	30 neurosurgical patients	90 patients in medical ICU	157 blunt trauma patients	53 neutropaenic patients	31 head injured patients	101 blunt trauma patients
Setting	Single neurosurgical unit, Singapore	Single medical ICU, USA	Single hospital, USA	Single ICU, France	Single neurosurgical unit, USA	Single hospital, USA
Age limits	Not stated	>17 years	Not stated	Not stated	Not stated	Not stated
Exclusions	Percutaneous tracheostomy	Transfers from other ICUs	Patients with craniofacial injuries	Not stated	Open gastrostomy*	Patients with craniofacial injuries
Early group definition	Tracheostomy before or on day 7	Tracheostomy before or on day 10 of mechanical ventilation	Tracheostomy before or on day 6 of mechanical ventilation	Tracheostomy before or on day 2	Tracheostomy before or on day 7	Tracheostomy before or on day 4
Late group definition	Tracheostomy after day 7	Tracheostomy after day 10	Tracheostomy after day 6	Tracheostomy after day 2	Tracheostomy after day 7	Tracheostomy after day 4
Tracheostomy technique	Surgical	Not stated	Not stated	Surgical	Percutaneous and surgical	Surgical (implied not stated)
Early/late n	12/18	53/37	62/95	20/33	21/10	32/69
ICU mortality early group	Not stated	Not stated	Not stated	14 (70%)	Not stated	Not stated
ICU mortality late group	Not stated	Not stated	Not stated	26 (79%)	Not stated	Not stated
Hospital mortality early group	Not stated	15 (28%)	7 (11.3%)	15 (75%)	2 (10%)	Not stated
Hospital mortality late group	Not stated	14 (37.8%)	11 (11.6%)	27 (82%)	1 (10%)	Not stated
ICU LOS early group (days)	Not stated	Mean 15.6 SD 9.3	Mean 15 SD 12	Mean 28 SD 24	Mean 12.6 SD not stated	Not stated
ICU LOS late group (days)	Not stated	Mean 29.3 SD 15.4	Mean 29 SD 26	Mean 19 SD 18	Mean 26.2 SD not stated	Not stated
Hospital LOS early group (days)	Not stated	Mean 44.8 SD 30.3	Mean 33 SD 24	Mean 31 SD 26	Not stated	Not stated
Hospital LOS late group (days)	Not stated	Mean 49.6 SD 22.3	Mean 68 SD 48	Mean 23 SD 21	Not stated	Not stated
Patients developing pneumonia, early group	Not stated	16 (30%)	Not stated	2 (10%)	Not stated	6 (19%)
Patients developing pneumonia, late group	Not stated	16 (43.2%)	Not stated	3 (9%)	Not stated	41 (59%)
Comments					* = All patients also had a percutaneous gastrostomy	

Literature search: Data to inform the protocol development and power calculations

APPENDIX 3

Section 1 of table

Reference number	Study type	Study topic	Year of publication	First author surname	Country	n Tracheostomy patients	Patient group
³⁵	Prospective case series	Single dilator technique	2003	Westphal	Germany	10	Long term ventilation patients
³⁶	Prospective case series	Complications of tracheostomy in ICU	2003	Francois	France	118	Mixed medical/surgical ICU patients
³⁷	Prospective case series	PDT	2003	Polderman	Netherlands	211	Mixed medical/surgical ICU patients
³⁸	Prospective case series	Nosocomial pneumonia in ICU patients with PDT	2003	Rello	Spain	110	Mixed medical/surgical ICU patients
³⁹	Prospective case series	PDT/ST	2003	Goldenberg	Israel	150	Ventilated head and neck surgery patients
⁴⁰	Randomised controlled trial (RCT)	Non-invasive ventilation/weaning	2003	Ferrer	Spain	22	Mixed medical/surgical ICU patients
⁴¹	Non-randomised controlled trial	PDT/ST	2003	Kaylie	USA	24	Mixed medical/surgical ICU patients
⁴²	Prospective case series	Translaryngeal tracheostomy	2003	Sharpe	Canada	340	Mixed medical/surgical ICU patients
⁴³	Prospective case series	Infective complications in PDT	2003	Jacobs	Saudi Arabia	228	Mixed medical/surgical ICU patients
⁴⁴	RCT	Bronchoscopy vs capnography for PDT	2003	Mallick	UK	55	Mixed medical/surgical ICU patients
⁴⁵	Prospective case series	Laryngotracheoscopic findings after Griggs tracheostomy	2002	Dollner	Germany	60	Cardiac surgery patients
⁴⁶	RCT	PDT/ST	2002	Melloni	Italy	50	Mixed medical/surgical ICU patients
⁴⁷	Prospective case series	PDT tube obstruction	2002	Trottier	USA	54	Mixed medical/surgical ICU patients
⁴⁸	Retrospective case series	Tracheostomy vs endotracheal intubation in neck infections	2002	Potter	USA	85	Hospital patients with deep neck space infections

Section 1 of table - Appendix 3 continued/...

Reference number	Study type	Study topic	Year of publication	First author surname	Country	n Tracheostomy patients	Patient group
49	Prospective before and after intervention study	Quality improvement programme on weaning	2002	Smyrnois	USA	738	Mixed medical/surgical ICU patients
50	RCT	Translaryngeal vs forceps-dilational technique	2002	Cantais	France	100	Mixed medical/surgical ICU patients
51	RCT	"Blue Rhino" vs PercuTwist	2002	Byhahn	Germany	70	Mixed medical/surgical ICU patients
52	Prospective case series	PDT/ST	2002	Khalili	USA	346	All tracheostomy patients
53	Prospective case series	Follow up after Griggs tracheostomy	2002	Dollner	Germany	162	Mixed medical/surgical ICU patients
54	RCT	PDT/ST	2002	Sustic	Croatia	16	Patients after anterior cervical fixation
55	Prospective case series	Controlled rotating dilation for PDT	2002	Frova	Germany	50	Mixed medical/surgical ICU patients
56	RCT	Ciaglia "Blue Rhino" vs Griggs guidewire dilating forceps	2002	Ambesh	India	60	Mixed medical/surgical ICU patients
12	RCT	Early vs late tracheostomy	2002	Saffle	USA	44	Critically ill burn patients
57	Retrospective case series	PDT/ST	2001	Bowen	USA	213	Mixed medical/surgical ICU patients
58	RCT	PDT/ST	2001	Massick	USA	164	Mixed medical/surgical ICU patients
19	Retrospective case series	Early vs late tracheostomy	2001	Teoh	Singapore	30	Neurological ICU patients
59	RCT	Single vs multiple dilator technique for PDT	2001	Johnson	USA	50	Patients with blunt trauma
60	RCT	PDT/ST	2001	Freeman	USA	80	Mixed medical/surgical ICU patients
61	Prospective case series	Griggs PDT with spiral CT	2000	Steele	UK	25	Mixed medical/surgical ICU patients available for 6 month follow up
62	Prospective case series	Bedside PDT with bronchoscopic guidance	2000	Hinerman	USA	50	Mixed medical/surgical ICU patients
63	Prospective case series	Ciaglia and Griggs techniques	2000	Anon	Spain	63	Mixed medical/surgical ICU patients

Section 1 of table – Appendix 3 continued/...

Reference number	Study type	Study topic	Year of publication	First author surname	Country	n Tracheostomy patients	Patient group
⁶⁴	Retrospective case series	Tracheostomy in ICU patients	2000	Fischler	Switzerland	1175	Mixed medical/surgical ICU patients
⁶⁵	Prospective case series	Bedside tracheostomy	2000	Velmahos	USA	100	Mixed medical/surgical ICU patients
⁶⁶	Prospective case series	Bedside PDT	2000	Kahveci	Turkey	72	Mixed medical/surgical ICU patients
⁶⁷	Prospective case series	Experience with PDT	2000	Lim	USA	311	Adult tracheostomy patients
²⁰	Prospective case series	Early vs late tracheostomy	2000	Brook	USA	90	Medical ICU patients
⁶⁸	Prospective case series	Two modified techniques vs basic technique for PDT	2000	Byhahn	Germany	75	Surgical ICU patients
⁶⁹	RCT	PDT/ST	2000	Heikkinen	Finland		Mixed medical/surgical ICU patients
⁷⁰	Prospective case series	Airway accidents	2000	Kapadia	India	79	Mixed medical/surgical ICU patients
⁷¹	Prospective case series	Ciaglia and Griggs techniques	2000	Kost	Canada	40	Mixed medical/surgical ICU patients
⁷²	RCT	Griggs vs Ciaglia	2000	Nates	USA	100	Mixed medical/surgical ICU patients
⁷³	RCT	Ciaglia "Blue Rhino" vs basic Ciaglia technique	2000	Byhahn	Germany	50	Mixed medical/surgical ICU patients
⁷⁴	Prospective case series	PDT/ST	2000	MacCallum	Canada	100	All tracheostomy patients
⁷⁵	RCT	PDTs vs guidewire dilating forceps	2000	Ven Heurn	Netherlands	127	Mixed medical/surgical ICU patients
⁷⁶	Prospective case series	Late outcome from PDT using Portex kit	1999	Leonard	Australia	80	Mixed medical/surgical ICU patients
⁷⁷	Prospective case series	Work of breathing pre and post tracheostomy	1999	Diehl	France	8	Medical patients
⁷⁸	Prospective case series	PDT/ST	1999	Suh	USA	96	Mixed medical/surgical ICU patients
⁷⁹	Prospective case series	Clinical predictors/outcomes in patients with tracheostomy	1999	Kollef	USA	51	Mixed medical/surgical ICU patients

Section 1 of table – Appendix 3 continued/...

Reference number	Study type	Study topic	Year of publication	First author surname	Country	n Tracheostomy patients	Patient group
⁸⁰	Prospective case series	PDT/ST	1999	Westphal	Germany	120	Patients after cardiac surgery
⁸¹	RCT	PDT/ST	1999	Porter	USA	70	Surgical ICU patients
⁸²	RCT	PDT/ST	1999	Gysin	Switzerland	70	All tracheostomy patients
⁸³	Retrospective case series	Long term complications	1998	Rosenbower	USA	237	Trauma patients
⁸⁴	Prospective case series	PDT/ST	1998	Van Natta	USA	272	Trauma patients
²⁴	Retrospective case series	Early vs late tracheostomy	1998	Armstrong	USA	157	Patients with blunt trauma
⁸⁵	Prospective case series	IV sedation/prolongation of mechanical ventilation	1998	Kollef	USA	242	Medical ICU patients
⁸⁶	Prospective case series	Long term outcome of PDT	1998	Walz	Germany	326	Mixed medical/surgical ICU patients
⁸⁷	RCT	Ciaglia vs Rapitrach method	1998	Ambesh	India	80	Mixed medical/surgical ICU patients
⁸⁸	RCT	PDT/ST	1998	Holdgaard	Denmark	60	All tracheostomy patients
⁸⁹	Prospective case series	Longterm outcome after PDT	1997	Law	UK	41	Survivors after PDT
⁹⁰	Retrospective case series	Tracheostomy timing in neuro-intensive care	1997	Koh	Singapore	17	Neurosurgical patients
⁹¹	Retrospective case series	Tracheostomy and the ICU patient	1997	Henrich	USA	100	Mixed medical/surgical ICU patients
⁹²	Prospective case series	Tracheal stenosis	1997	Callanan	UK	9	Mixed medical/surgical ICU patients
²⁸	Retrospective case series	Predicting ventilator dependence	1997	Sellers	USA	110	Patients with burns
⁹³	Prospective case series	PDT/ST	1997	Stoekli	Switzerland	83	Patients with upper GI/respiratory tumours
¹⁷	RCT	Early vs late tracheostomy	1997	Sugerman	USA	155	Level 1 trauma centre patients
⁹⁴	Prospective case series	PDT for airway control	1997	Carrillo	USA	35	Patients with blunt trauma
⁹⁵	Prospective case series	Perioperative complications of tracheostomy	1997	Berrouschof	Germany	76	Neurological ICU patients
⁹⁶	Prospective case series	PDT/ST	1997	Reilly	USA	15	Surgical ICU patients

Section 1 of table – Appendix 3 continued/...

Reference number	Study type	Study topic	Year of publication	First author surname	Country	n Tracheostomy patients	Patient group
⁹⁷	Prospective case series	PDT in medical ICU	1997	Petros	Germany	137	Mixed medical/surgical ICU patients
⁹⁸	Prospective case series	Bronchoscopic guidance	1996	Fernandez	USA	162	Mixed medical/surgical ICU patients
⁹⁹	Prospective case series	PDT	1996	Hill	USA	353	Mixed medical/surgical ICU patients
¹⁰⁰	Prospective case series	Percutaneous dilatational cricothyroidotomy	1996	Barrachina	Spain	44	Mixed medical/surgical ICU patients
¹⁰¹	Retrospective case series	PDT/ST	1996	Graham	USA	60	Mixed medical/surgical ICU patients
¹⁰²	Prospective case series	Evaluating Ciaglia PDT and Portex PDT technique	1996	Van Heerden	Australia	53	Mixed medical/surgical ICU patients
¹⁰³	RCT	PDT/ST	1996	Friedman	USA	53	Mixed medical/surgical ICU patients
²¹	Retrospective case series	Early vs late tracheostomy	1995	Blot	France	53	Neutropaenic patients
¹⁰⁴	Non-randomised controlled trial	PDT/ST	1995	Crofts	Canada	53	Mixed medical/surgical ICU patients
¹⁰⁵	Retrospective case series	Late outcome of PDT	1995	Fischler	Switzerland	16	ICU survivors of PDT (>2/12)
¹⁰⁶	Retrospective case series	Bedside vs operating room tracheostomies	1995	Lujan	USA	43	Patients with burns
⁵⁷	Retrospective case series	Bedside tracheostomy	1995	Upadhyay	USA	470	Mixed medical/surgical ICU patients
¹⁰⁷	RCT	PDT/ST	1994	Cole	Australia	55	Mixed medical/surgical ICU patients
²²	Prospective case series	Early vs late tracheostomy	1994	D'Amelio	USA	31	Head injured patients
¹⁰⁸	Prospective case series	Beside PDT with endoscopic guidance	1994	Winkler	Austria	71	Medical ICU patients
¹⁰⁹	Prospective case series	Bedside percutaneous tracheostomy	1993	Freidman	USA	100	Mixed medical/surgical ICU patients
¹¹⁰	Retrospective case series	Safety and efficacy of bedside tracheostomy	1993	Futran	USA	1088	Mixed medical/surgical ICU patients
¹¹¹	Retrospective case series	Early criteria predictive of prolonged mechanical ventilation	1992	Johnson	USA	91	Mixed medical/surgical ICU patients

Section 1 of table – Appendix 3 continued/...

Reference number	Study type	Study topic	Year of publication	First author surname	Country	n Tracheostomy patients	Patient group
²³	Retrospective case series	Early vs late tracheostomy	1992	Lesnik	USA	101	Patients with blunt trauma
¹¹²	Prospective case series	Long term follow up	1992	Ciaglia	USA	165	Mixed medical/surgical ICU patients
¹¹³	RCT	PDT/ST	1991	Hazard	USA	46	Mixed medical/surgical ICU patients
¹¹⁴	Prospective case series	Endoscopic guided PDT: early results	1990	Marelli	Canada	61	Mixed medical/surgical ICU patients
²⁶	Retrospective case series	Clinical features predicting long term ventilation	1990	Heffner	USA	11	Patients with ARDS
¹⁸	RCT	Early vs late tracheostomy	1990	Rodriguez	USA	106	Patients with blunt trauma
¹¹⁵	Retrospective case series	Intubation vs tracheostomy	1988	Astrachan	USA	52	Mixed medical/surgical ICU patients
¹¹⁶	Prospective case series	Tracheostomies in burn patients	1988	Jones	USA	99	Patients with burns
¹¹⁷	Prospective case series	Perioperative complications of elective tracheostomy	1986	Stock	USA	81	Mixed medical/surgical ICU patients
¹¹⁸	Retrospective case series	Review of complications	1986	Dayal	USA	50	Mixed medical/surgical ICU patients
⁸	Prospective case series	Elective PDT	1985	Ciaglia	USA	24	Mixed medical/surgical ICU patients
¹¹⁹	Retrospective case series	Complications of tracheostomy in neurosurgical patients	1984	Miller	USA	84	Neurosurgical patients with tracheostomy
³²	RCT	Early vs late tracheostomy	1984	Dunham	USA	74	Patients with blunt trauma
¹²⁰	Retrospective case series	Local complications and mortality	1983	Schusterman	USA	214	Mixed medical/surgical ICU patients
¹²¹	Retrospective case series	Complications of tracheostomy	1981	Arola	Turkey	794	All tracheostomy patients
³³	RCT	Early vs late tracheostomy	1981	Stauffer	USA	150	Mixed medical/surgical ICU patients
³⁴	RCT	Early vs late tracheostomy	1976	El-Nagger	USA	52	Patients with acute respiratory failure

Section 1 of table – Appendix 3 continued/...

Reference number	Study type	Study topic	Year of publication	First author surname	Country	n Tracheostomy patients	Patient group
¹²²	Prospective case series	Tracheostomy complicating massive burn injury	1974	Eckhauser	USA	25	Patients with >55% burns
¹²³	Retrospective case series	Tracheostomy in thermally ill patients	1972	Moylan	USA	280	Burns patients
¹²⁴	RCT	Tracheal injury	1971	Grillo	USA	90	All tracheostomy patients
¹²⁵	Retrospective case series	Tracheostomy management, mortality, complications	1969	Skaggs	USA	147	Males requiring tracheostomy
¹²⁶	Retrospective case series	Complications of tracheostomy	1969	Mulder	USA	428	Mixed medical/surgical ICU patients
¹²⁷	Retrospective case series	Tracheotomy in burns	1959	Moncrief	USA	138	Patients with burns
⁵	Prospective case series	Tracheostomy in poliomyelitis	1953	Lasson	Denmark	150	Poliomyelitis patients

Section 2 of table - Appendix 3 continued

Reference number	Percutaneous or surgical tracheostomy	Day tracheostomy carried out after intubation () = range, [] = SD	Operative mortality	Patients with tracheostomy hospital mortality	Patients without tracheostomy hospital mortality	Patients with tracheostomy ICU length of stay, days	Patients without tracheostomy ICU length of stay, days	Other comments
35	PDT	7.1 [2.4]	0.0%					
36	Surgical	12 [7] cricothyroid; 14 [9] subthyroid; mean 13.5	0.0%			37.2		
37	Both	11.8 [8.2]	0.0%	9.1%		6.1 [5.3]		
38	Both	13 median (1-29)						
39	Both	9.4 [2.1] surgical; 7.8 [0.4] PDT	0.0%					
40	Both							
41	Both							
42	PDT	12 [6]	0.0%					
43	PDT	7.8		43.0%		8.9		
44	Both	4.3						
45	PDT	9 (2-78)		47.0%				1200 patients, 93 ventilated>5 days, 60/93 (64.5%) tracheostomy
46	Both	7.5 [3.1] surgical; 6.9 [2.4] PDT, mean 7.2		11.0%				
47	PDT							
48	Surgical		0.0%	0.0%	2.0%	1.1	3.1	
49				29.7%	29.7%	39.9	10.4	
50	PDT	20 translaryngeal, 17 PDT						
51	PDT	9.5						
52	Both		0.0%	35.0%				
53	PDT			50.6%				

Section 2 of table – Appendix 3 continued/...

Reference number	Percutaneous or surgical tracheostomy	Day tracheostomy carried out after intubation () = range, [] = SD	Operative mortality	Patients with tracheostomy hospital mortality	Patients without tracheostomy hospital mortality	Patients with tracheostomy ICU length of stay, days	Patients without tracheostomy ICU length of stay, days	Other comments
54	Both	18 surgical; 16 PDT; mean 17		25.0%		21		
55	PDT		0.0%					
56	PDT	8.5		45.0%				
12				81.0%	74.0%			
57	Both	11.9 PDT; 14.3 surgical						
58	Both	9.7 [4.1]	0.0%					
19	Surgical							
59	PDT							
60	Both			45.0%		27		
61	PDT	9.5 (3-24)						Approximately 8400 patients, 106/8400 (1.3%) tracheostomy
62	PDT	17	0.0%	40.0%				
63	PDT	19.8 [1.2]						
64								
65	PDT	12		36.5%				
66	PDT							
67	Both		0.0%					
20	PDT	5.9 [7.2] early; 16.7 [2.9] late		28.3%	37.8%	15.6 [9.3]	29.3 [15.4]	
68	PDT	10.5		64.0%				
69	Both	11.5 PDT; 13.0 surgical; mean 12.2						
70								
71	Both			15.0%				
72	PDT	6.3						
73	PDT	7.35		36.0%				
74	Both							

Section 2 of table – Appendix 3 continued/...

Reference number	Percutaneous or surgical tracheostomy	Day tracheostomy carried out after intubation () = range, [] = SD	Operative mortality	Patients with tracheostomy hospital mortality	Patients without tracheostomy hospital mortality	Patients with tracheostomy ICU length of stay, days	Patients without tracheostomy ICU length of stay, days	Other comments
75	PDT			32.2%				
76	PDT			67.5%				
77								
78	PDT	10.5	2.0%	38.9%				
79		9.7 [6.4]		13.7%	26.4%	18.8 [15.5]	5.7 [6.7]	
80	PDT	18 surgical, 13 PDT; 9 translaryngeal						
81	Both	15.6	1.4%					
82	Both	4.9 [7.5] surgical; 8.3 [12.4] PDT; mean 6.6		28.6%				
83	Both	10.5 (2-32)	0.0%					
84	PDT		0.0%					
24						24 [23]		
85								Tracheostomy rate overall 11.6%
86	PDT		0.6%					
87	PDT	11.5		65.0%				
88	Both							
89	PDT	7 (1-21)						
90						14.3		
91	Both							
92	PDT	7.7						
28								
93	Both		0.1%	28.9%				
17	Both	3-5 early; >14 late		24.5%	18.6%	20 [2]	24 [2]	
94	PDT	8 [5]		5.7%				
95	PDT		0.1%					
96	Both							
97	PDT	8						
98	PDT	12.2		15.4%				
99	PDT	14 [8]	0.3%	25.0%		26 [50]		
100	PDT			53.4%				

Section 2 of table – Appendix 3 continued/...

Reference number	Percutaneous or surgical tracheostomy	Day tracheostomy carried out after intubation () = range, [] = SD	Operative mortality	Patients with tracheostomy hospital mortality	Patients without tracheostomy hospital mortality	Patients with tracheostomy ICU length of stay, days	Patients without tracheostomy ICU length of stay, days	Other comments
101	Both	9.19 PDT; 8.59 surgical mean 8.9		28.3%				
102	PDT		0.0%					
103	Both	17.2 [7.5] PDT, 21.3 [26.2] surgical; mean 19.2		35.8%				
21	PDT	2	0.0%	75.0%		28 [24]		
104	Both	12.5 [6.3] surgical; 10.5 [5.0] PDT; mean 11.4	0.0%					
105	PDT							
106	Surgical		0.0%	34.9%				
57	Surgical	12.8	0.0%					
107	PDT		0.0%					
22	PDT			9.7%		17		
108	PDT	12	0.0%					
109	PDT	14.5 [12.0]	0.0%	63.0%				
110	Surgical		0.0%	5.3%				
111								
23								
112	PDT		0.0%					
113	Both	9.2 [3.2] surgical; 7.7 [3.9] PDT; mean 8.5		43.0%				
114	PDT	17 (2-68)	0.0%	46.0%				
26	Surgical	21 [3]						
18		4 [0.4] or 11 [0.4]	0.0%	18.0%	23.0%	16 [1]	37 [1]	
115	Surgical	10						
116	Surgical			74.7%				3246 patients, 99/3426 (28.9%) tracheostomy
117	Surgical	8 (1-15)	0.0%					
118	Surgical	7.7 (1-13)		32.0%				

Section 2 of table – Appendix 3 continued/...

Reference number	Percutaneous or surgical tracheostomy	Day tracheostomy carried out after intubation () = range, [] = SD	Operative mortality	Patients with tracheostomy hospital mortality	Patients without tracheostomy hospital mortality	Patients with tracheostomy ICU length of stay, days	Patients without tracheostomy ICU length of stay, days	Other comments
⁸	PDT		0.0%	54.0%				
¹¹⁹	Surgical			39.0%				
³²	Surgical	3-4 or 14						
¹²⁰	Surgical		0.4%					
¹²¹	Surgical	3.3	6.0%	46.0%				
³³		7.4	0.0%					
³⁴	Surgical	3 or >10						
¹²²	Surgical			44.0%	56.0%			
¹²³	Surgical		0.0%	52.0%	16.2%			
¹²⁴	Surgical							
¹²⁵	Surgical			61.0%				
¹²⁶	Surgical			39.0%				
¹²⁷			0.0%	57.0%	19.3%			
⁵	Surgical			47.0%				
Unweighted mean values		10.8 days	0.3%	38.1%	30.3%	20.1 days	18.3 days	

The questionnaire sent out:

TRACHEOSTOMY SHEET

COLLECTING TRACHEOSTOMY INFORMATION

Dear

We would be extremely grateful if you could supply the following information from your hospital relating to tracheostomy.

- 1 **Number of percutaneous tracheostomy kits (not tracheostomy tubes) ordered in a one year period?**

Tracheostomy kits ordered in period ____/____/____ to ____/____/____
Number here Day month year Day month year

- 2 **Number of tracheostomies performed in a one year period?**

Tracheostomies performed in period ____/____/____ to ____/____/____
Number here Day month year Day month year

- 3 **How many patients who had a tracheostomy died (in ICU) in a one year period?**

Number of deaths in period ____/____/____ to ____/____/____
Number here Day month year Day month year

- 4 **Number of intensive care unit admissions for a one year period?**

Admissions in period ____/____/____ to ____/____/____
Number here Day month year Day month year

- 5 **Do you have a computerised information system in the ICU? (tick one)**

No Yes → specify type: (Carevue etc) _____

- 6 **Who is the best person to contact regarding your computer information system?**

Name: _____ Title: _____

- 7 **Please confirm the name of the hospital you have collected this data from below:**

Hospital name: _____ Town/City: _____

**Thank you in advance for your help.
 Please return this sheet in the Freepost envelope provided.**

Enquiries to: Lesley Morgan, Research Co-ordinator, ICS Trials Group, Kadoorie Centre for Critical Care Research and Education,
 John Radcliffe Hospital, Oxford OX3 9DU. Tel: 01865 857627 Email: lesley.morgan@nda.ox.ac.uk

The results:

Hospital code number	Tracheostomies/year	Admissions/year	Tracheostomy rate as % of all admissions	ICU mortality in tracheostomised patients as %
7	12	251	4.8	58.2
22	17			
26	36	137	26.3	27.9
18	22	364	6.0	
13	24	191	12.6	12.5
30	24	626	3.8	33.2
21	24	435	5.5	
15	25			
40	26	369	7.1	19.2
25	33	395	8.4	12.1
38	33	509	6.5	21.2
5	34	507	6.7	
10	35	493	7.1	25.7
31	36	472	7.6	11.1
37	40	419	9.6	
19	46	355	13.0	23.9
23	53			
4	55			
39	59	1023	5.8	
29	61	298	20.5	21.3
1	61			
11	67			
9	70	373	18.8	17.1
27	77	377	20.5	20.7
3	85	328	25.9	18.8
8	79	841	9.4	12.6
28	83			
12	96	398	24.2	12.5
2	97	468	20.8	11.3
41	99			9.1
33	119	337	35.3	
32	133	737	18.1	21.0
17	170	350	48.6	32.4
36	175	669	26.2	9.7
16	180	415	43.4	
Mean	65	450	16	21
Max	180	1023	49	58
Min	12	137	4	9

APPENDIX 5

DOCUMENTATION FOR ADULTS WHO HAVE CAPACITY TO CONSENT

Process for obtaining consent from Adults who **have** the capacity to consent
prior to trial entry

Patient fulfils eligibility criteria	
YES	NO
<ul style="list-style-type: none"> • Explanation to be given in person • Written consent to be obtained • Local investigators will ensure that the patient receives a copy of the consent form, and that a copy is placed in the patient's notes. The top copy consent form must be filed in the TracMan Binder 2 at the collaborating hospital. • If the patient refuses to consent, they cannot be entered into the trial. Local investigators should complete the Patient Screening Log. 	<ul style="list-style-type: none"> • The patient cannot be entered into the trial
<p><i>Under the English Mental Capacity Act 2005 a person lacking capacity is defined as:</i> Someone unable</p> <ul style="list-style-type: none"> • <i>to understand information relevant to the decision</i> • <i>to retain that information</i> • <i>to use or weigh that information</i> • <i>to communicate a decision</i> <p><i>and this is deemed to be situation specific</i></p> <p>The High Court (England) held that an adult has capacity to consent if:</p> <ul style="list-style-type: none"> • he or she can understand and retain the information relevant to the decision in question • believe that information • weigh that information in the balance to arrive at a choice <p>The quality of consent should be ascertained from the responses given. Questions should be encouraged, and an opportunity to clarify information provided.</p>	

Documentation to use is detailed over the page.

[On local hospital headed paper]

TracMan Study

Centre No.

PATIENT INFORMATION SHEET

Version 9 – 6 March 2006
MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator [name and telephone number here]

You are being invited to take part in a research study while you are here as a patient in the intensive care unit. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and, if you wish, to discuss it with your relatives or friends. Ask us if there is anything that is unclear or if you would like more information. Thank you for reading this.

What is the purpose of the study?

Patients who need help with their breathing (artificial ventilation) have a tube placed through their mouths into their lungs. This tube is connected to the machine that assists their breathing.

If patients require assistance with their breathing for long periods of time, the tube that goes into the lungs via the mouth is often changed to one that goes through an incision in the front of the windpipe (trachea) in the neck. This is called a tracheostomy. Tracheostomy is an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units.

At present we do not know if it is better to perform a tracheostomy in the early stages (first 4 days) of a patient's illness, or wait until 10 days or more. By doing the tracheostomy earlier, patients may recover faster, but by doing it later some patients may avoid the need for a tracheostomy altogether. Doctors really do not know which is best.

The Intensive Care Society, a professional body representing most of the doctors working in Intensive Care Units in the UK, is trying to find the answer. It is conducting a national study involving over 1200 intensive care patients in many hospitals around the UK. This will compare the progress of patients who receive "early" or "late" tracheostomy.

This study has been reviewed and approved by a Research Ethics Committee.

Why have I been chosen?

Your doctors believe that it will take another 7 or more days before you will be able to breathe on your own without any help from a ventilator (breathing machine).

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form, a copy of the consent form will be given to you.

What will happen to me if I take part?

Sometimes because we do not know which way of treating patients is best, we need to make comparisons. People are put into groups and then compared. The groups are selected by a computer that will decide on a chance basis (as if it were tossing a coin) whether you will receive an "early" tracheostomy (on day 1-4 of your ICU stay), or a "late" tracheostomy after you have been in the Intensive Care Unit for 10 days or more. If you are in the "late" group you may not need a tracheostomy at all. Once we know what group you are in we will treat you accordingly. All other care will continue in the usual manner. There are no extra tests involved in taking part in this research. The chances of being selected for either group are equal.

As part of the study routine information on your treatment will be collected. In addition, appropriate personal identifying details will be collected to enable us to be kept informed about your health once you have left the Intensive Care Unit. It is possible that we will contact your GP to see how you are doing, or we may follow your health through a government agency called the Office of National Statistics which is told about all the births and deaths in the United Kingdom. If you decide not to allow us to follow up your health status, then we will abide by your wishes and not collect follow up data on you. You do not have to give a reason, and the standard of care you receive will not be affected.

What do I have to do?

You do not have to do anything yourself. The doctors and nurses on the Intensive Care Unit will keep you informed at all times.

What are the possible risks and benefits of taking part?

This trial is evaluating the best time to perform a tracheostomy. The risks related to the tracheostomy procedure are the same whether you take part in the study, or have a tracheostomy outside of the study. The possible risks of taking part in the study is that there is a small chance you might not have needed a tracheostomy as early as the first four days of your ICU stay. The potential benefit of taking part is that by having a tracheostomy early you may require less sedative drugs during your ICU stay.

What if something goes wrong?

This study is investigating an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part be kept confidential?

All information that is collected about you during the course of the research study will be kept strictly confidential. Your identifying details will be held in a secure environment and only accessed by the research team for the purposes of follow up.

What will happen to the results of the research study?

The study is estimated to take around three years, it started in the Autumn of 2004. It is hoped to publish the results in 2008 on the Intensive Care Society's web page (www.ics.ac.uk). If you would like a copy of the published results, please contact the Principal Local Investigator (name given above).

Who is funding the study?

The Medical Research Council and the Intensive Care Society, a UK charity, have both contributed to the funding of this study.

Contact for further information

If you would like further information, please feel free to contact [Principal Local Investigator name and telephone number], the consultant leading the study on this unit.

[On local hospital headed paper]

Centre No.

TracMan Study

PATIENT CONSENT FORM

Version 8 – 20 September 2004
MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

- | | | |
|---|---|----------------------|
| 1 | I confirm that I have read and understand the information sheet dated [date and version here] for the above study and have had the opportunity to ask questions | <input type="text"/> |
| 2 | I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected | <input type="text"/> |
| 3 | I understand that sections of any of my medical notes may be looked at by responsible individuals involved with the study. I give permission for these individuals to have access to my records | <input type="text"/> |
| 4 | I give permission for my personal identifying information to be collected, stored and used by the study office to enable follow up of my health status. This is on the understanding that any information will be treated with the strictest security and confidentiality | <input type="text"/> |
| 5 | I give permission for appropriate personal identifying information to be passed onto the Office of National Statistics for the purposes of following up my health status | <input type="text"/> |
| 6 | I give permission for my GP to be contacted about my health status | <input type="text"/> |
| 7 | I give permission for information about me to be gathered from the Office of National Statistics through the flagging system for follow up purposes | <input type="text"/> |
| 8 | I agree to take part in the above study | <input type="text"/> |

Name of patient	Date	Signature
Name of person taking consent (if not Principal Local Investigator)	Date	Signature
Name of Principal Local Investigator	Date	Signature

Photocopy x 2: 1 copy for patient, 1 copy for patients hospital notes, top copy for Principal Investigator's study file,

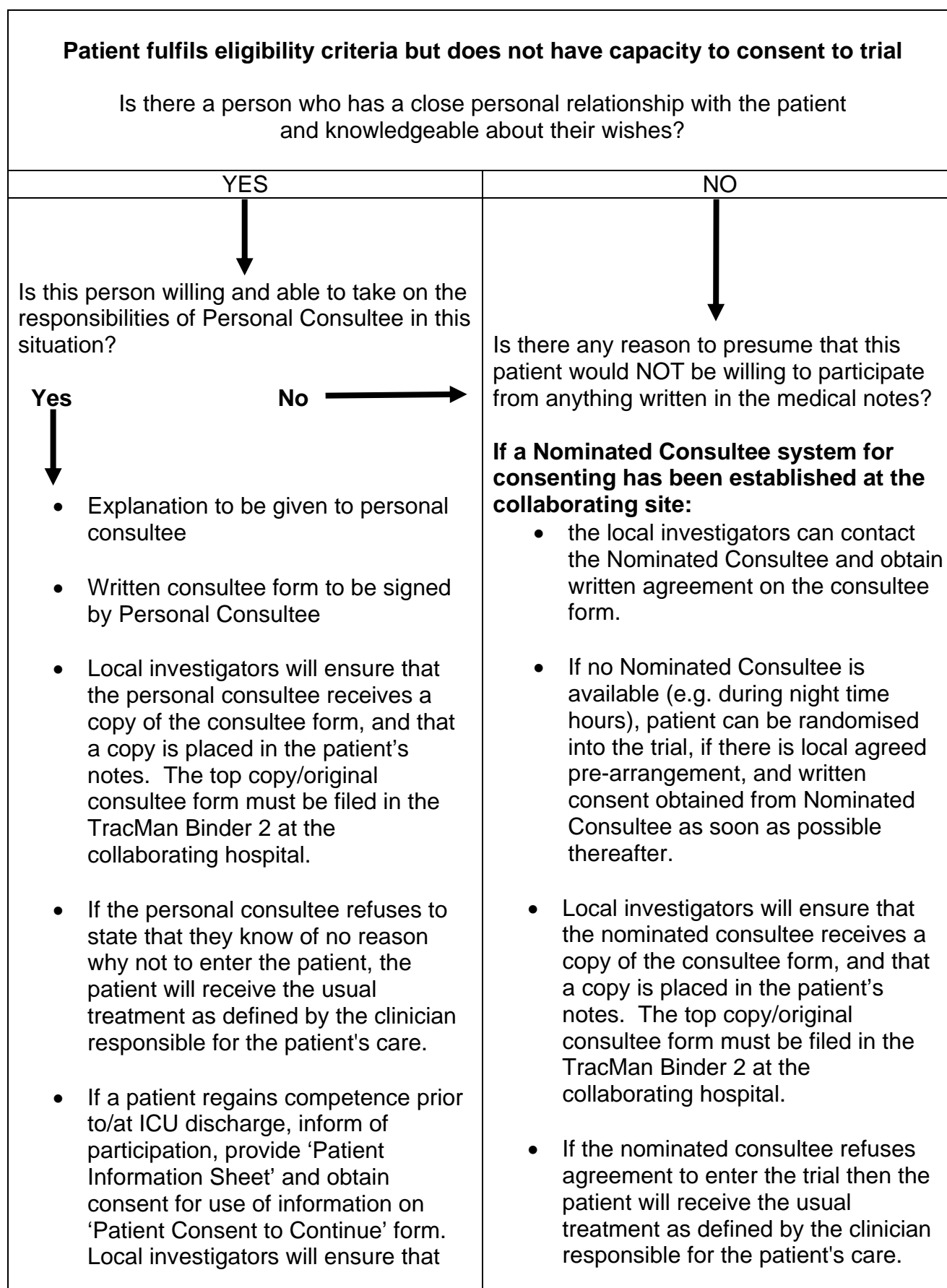
APPENDIX 6

CONSENT PROCESS AND DOCUMENTATION
FOR ADULTS IN THE INTENSIVE CARE UNIT
WHO DO **NOT** HAVE CAPACITY TO CONSENT

ENGLAND AND WALES

THE MENTAL CAPACITY ACT 2005
(IMPLEMENTED IN 2007)

**Process for obtaining consent in England and Wales:
Hospitals falling under the Mental Capacity Act 2005 (England and Wales)**



<p>the patient receives a copy of the consent form, and that a copy is placed in the patient's notes. The top copy/original consent form must be filed in the TracMan Binder 2 at the collaborating hospital.</p> <ul style="list-style-type: none"> • If the patient refuses to continue in the trial (i.e.after randomisation), they are free to withdraw. Local investigators will ensure that the 'Withdrawal from trial' sheet in the Patient Data Booklet Is completed and returned to the trial office.as soon as possible <p>THERE MAY BE SITUATIONS WHERE THERE IS A PERSONAL CONSULTEE FOR THE PATIENT, BUT THEY ARE UNABLE TO VISIT and therefore are unable to SIGN A CONSULTEE FORM, IN THESE CASES A VERBAL PERSONAL CONSULTEE FORM SHOULD BE COMPLETED AND WRITTEN CONSULTEE AGREEMENT OR PATIENT CONSENT SUBSEQUENTLY SOUGHT.</p>	<ul style="list-style-type: none"> • If patient regains competence prior to/at ICU discharge, inform of participation, provide Patient Information Sheet and obtain consent for use of information on 'Patient Consent to Continue' form. Local investigators will ensure that the patient receives a copy of the consent form, and that a copy is placed in the patient's notes. The top copy/original consent form must be filed in the TracMan Binder 2 at the collaborating hospital. • If the patient refuses to continue in the trial (i.e.after randomisation), they are free to withdraw. Local investigators will ensure that the 'Withdrawal from trial' sheet in the Patient Data Booklet Is completed and returned to the trial office.as soon as possible <p>If no Nominated Consultee system established locally:</p> <ul style="list-style-type: none"> • The patient cannot be entered into the trial
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This research is being carried out in accordance with sections 30-33 of the Mental Capacity Act 2005 to be implemented in 2007. The Mental Capacity Act will apply to research involving people without capacity, whether temporarily or permanently, and whether the incapacity is due to being unconscious, illness or learning disability. The Act provides a statutory framework to empower and protect vulnerable people who are not able to make their own decisions. It makes it clear who can take decisions, in which situations and how they should go about this. It enables people to plan ahead for a time when they may lose capacity. See <http://www.dh.gov.uk/assetRoot/04/13/86/62/04138662.pdf> (downloaded 9 March 2007).

*Under the English Mental Capacity Act 2005 a person **lacking capacity** is defined as:*
Someone unable

- *to understand information relevant to the decision*
- *to retain that information*
- *to use or weigh that information*
- *to communicate a decision*

and this is deemed to be situation specific

The High Court (England) held that an adult **has capacity** to consent if:

- he or she can understand and retain the information relevant to the decision in question
- believe that information
- weigh that information in the balance to arrive at a choice

The quality of consent should be ascertained from the responses given. Questions should be encouraged, and an opportunity to clarify information provided.

If a patient dies before regaining consciousness and the legal representative has given consent, the patient's data will be included in the study.

Documentation to use is detailed over the page.

[On local hospital headed paper]

Centre No.

TracMan Study

**COVERING STATEMENT FOR
NOMINEES**

(to be given out with the Patient Information Sheet)

Version 1 - 26 October 2007
MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

We are giving you this sheet as a person close to you is currently in the intensive care unit. We would like this person to take part in a research study while he/she is a patient in this intensive care unit. Unfortunately, **they are not** well enough to be able to decide whether or not to participate. Legally*, you **are not able to give consent** on his/her behalf to take part in a study, however we can ask you to give your opinion of whether your relative/friend/partner would wish to take part in a study.

Before you decide, we ask you to read the Patient Information Sheet carefully and let us know if you would like to **give your agreement** to their taking part in the study.

When patients who enter this study regain consciousness and have the ability to understand the purpose of this study, we will explain the study to them and **ask for their consent to continue in the study.**

If you have further questions either now or at any time subsequently, please feel free to contact [name of consultant and telephone number], the consultant leading the study on this unit.

Thank you for your time in considering this request.

Attached: Patient Information Sheet
**Mental Capacity Act 2005*

[On local hospital headed paper]

Centre No.

TracMan Study

PATIENT INFORMATION SHEET

Version 9 – 6 March 2006
MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator [name and telephone number here]

You are being invited to take part in a research study while you are here as a patient in the intensive care unit. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and, if you wish, to discuss it with your relatives or friends. Ask us if there is anything that is unclear or if you would like more information. Thank you for reading this.

What is the purpose of the study?

Patients who need help with their breathing (artificial ventilation) have a tube placed through their mouths into their lungs. This tube is connected to the machine that assists their breathing.

If patients require assistance with their breathing for long periods of time, the tube that goes into the lungs via the mouth is often changed to one that goes through an incision in the front of the windpipe (trachea) in the neck. This is called a tracheostomy. Tracheostomy is an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units.

At present we do not know if it is better to perform a tracheostomy in the early stages (first 4 days) of a patient's illness, or wait until 10 days or more. By doing the tracheostomy earlier, patients may recover faster, but by doing it later some patients may avoid the need for a tracheostomy altogether. Doctors really do not know which is best.

The Intensive Care Society, a professional body representing most of the doctors working in Intensive Care Units in the UK, is trying to find the answer. It is conducting a national study involving over 1200 intensive care patients in many hospitals around the UK. This will compare the progress of patients who receive "early" or "late" tracheostomy.

This study has been reviewed and approved by a Research Ethics Committee.

Why have I been chosen?

Your doctors believe that it will take another 7 or more days before you will be able to breathe on your own without any help from a ventilator (breathing machine).

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form, a copy of the consent form will be given to you.

What will happen to me if I take part?

Sometimes because we do not know which way of treating patients is best, we need to make comparisons. People are put into groups and then compared. The groups are selected by a computer that will decide on a chance basis (as if it were tossing a coin) whether you will receive an "early" tracheostomy (on day 1-4 of your ICU stay), or a "late" tracheostomy after you have been in the Intensive Care Unit for 10 days or more. If you are in the "late" group you may not need a tracheostomy at all. Once we know what group you are in we will treat you accordingly. All other care will continue in the usual manner. There are no extra tests involved in taking part in this research. The chances of being selected for either group are equal.

As part of the study routine information on your treatment will be collected. In addition, appropriate personal identifying details will be collected to enable us to be kept informed about your health once you have left the Intensive Care Unit. It is possible that we will contact your GP to see how you are doing, or we may follow your health through a government agency called the Office of National Statistics which is told about all the births and deaths in the United Kingdom. If you decide not to allow us to follow up your health status, then we will abide by your wishes and not collect follow up data on you. You do not have to give a reason, and the standard of care you receive will not be affected.

What do I have to do?

You do not have to do anything yourself. The doctors and nurses on the Intensive Care Unit will keep you informed at all times.

What are the possible risks and benefits of taking part?

This trial is evaluating the best time to perform a tracheostomy. The risks related to the tracheostomy procedure are the same whether you take part in the study, or have a tracheostomy outside of the study. The possible risks of taking part in the study is that there is a small chance you might not have needed a tracheostomy as early as the first four days of your ICU stay. The potential benefit of taking part is that by having a tracheostomy early you may require less sedative drugs during your ICU stay.

What if something goes wrong?

This study is investigating an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part be kept confidential?

All information that is collected about you during the course of the research study will be kept strictly confidential. Your identifying details will be held in a secure environment and only accessed by the research team for the purposes of follow up.

What will happen to the results of the research study?

The study is estimated to take around three years, it started in the Autumn of 2004. It is hoped to publish the results in 2008 on the Intensive Care Society's web page (www.ics.ac.uk). If you would like a copy of the published results, please contact the Principal Local Investigator (name given above).

Who is funding the study?

The Medical Research Council and the Intensive Care Society, a UK charity, have both contributed to the funding of this study.

Contact for further information

If you would like further information, please feel free to contact [Principal Local Investigator name and telephone number], the consultant leading the study on this unit.

[On local hospital headed paper]

Centre No.

TracMan Study

CONSULTEE FORM

Version 1 – 26 October 2007

MainREC number: 04/MRE00/43

Regarding patient (please write patients name here): _____

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

- 1 I confirm that I have read and understand the information sheet dated [date and version here] for the above study and have had the opportunity to ask questions
- 2 I confirm that I am voluntarily stating that I know of no reason why the above patient would not wish to take part in the study and that once they regain capacity they will be free to withdraw at any time, without giving any reason, and without their medical care or legal rights being affected.....
- 3 I confirm that I am acting as consultee for the above named person who is currently incapacitated, and know of no reason why the patient would not want to take part in the TracMan study. In addition, I am not aware of any advanced statements that would prevent them from taking part in the study.....
- 4 I agree that sections of their medical record can be looked at by responsible individuals involved with the study and transcribed onto the study form.....
- 5 I agree that appropriate personal identifying information will be collected, stored and used by the study office to enable follow up of health status. This is on the understanding that any information will be treated with the strictest security and confidentiality.....
- 6 I agree to their GP being contacted about their health status in the future.....
- 7 I agree that information about the patient can be gathered from the Office of National Statistics through the flagging system for follow up purposes.....
- 8 My relationship to the patient is: _____
(please write your relationship to the patient here, for example wife/partner/brother etc.
Or Nominated Consultee)

Name (PRINT) of Consultee	Date	Signature
---------------------------	------	-----------

Name of person informing consultee (if not Principal Local Investigator)	Date	Signature
---	------	-----------

Name of Principal Local Investigator	Date	Signature
--------------------------------------	------	-----------

Photocopy x 2: 1 copy for consultee, 1 copy for patients hospital notes, top copy for Principal Investigator’s study file,

[On local hospital headed paper]

Centre No.

TracMan Study

PERSONAL CONSULTEE VERBAL FORM

Version 1 – 26 October 2007
MainREC number: 04/MRE00/43

Use this form if there is a personal consultee for the patient but they are unable to get in to sign the consultee form

Regarding patient (please write patients **name** here): _____

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

1 I confirm that the patient’s inclusion in the above study has been discussed with the Personal consultee and that they were offered the opportunity to ask questions/ask for clarification.....

2 I confirm he/she has given stated that they so not know of any reason why the above patient would not wish to take part in the study and that once they regain capacity they will be free to withdraw at any time, without giving any reason, and without their medical care or legal rights being affected.....

3 I confirm he/she understands that personal identifying details will be collected for this patient and that he/she has given agreement for this information to be collected, stored and used for follow up purposes

4 I confirm he/she understands that the patients GP and the Office of National Statistics may be contacted for the purposes of following up the health status of the patient.....

4 The personal consultee’s relationship to the patient is that of: _____

Please initial box

5 A copy of the Covering Statement and Patient Information Sheet has been given or sent to the personal consultee (please tick as appropriate): Yes No

Name of personal consultee

Date

Name of person informing personal consultee (if not Principal Local Investigator)

Date

Signature

Name of Principal Local Investigator

Date

Signature

Photocopy x 2: 1 copy for personal consultee, 1 copy for patients hospital notes, top copy for Principal Investigator’s study file,

[On local hospital headed paper]

Centre No.

TracMan Study

PATIENT INFORMATION SHEET: CONSENT TO CONTINUE**Version 1 - 9 March 2007**

MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

During your stay in the intensive care unit you took part in a research study that is currently taking place in many intensive care units throughout the UK. It is important for you to understand why the research is being done and what it involves. Please read the following information carefully and, if you wish, discuss it with your relatives or friends. Ask if there is anything that is unclear or if you would like any more information. Thank you for reading this.

What is the purpose of this study?

Patients who need help with their breathing (artificial ventilation) have a tube placed through their mouths into their lungs. This tube is connected to the machine that assists their breathing.

If patients require assistance with their breathing for long periods of time, the tube that goes into the lungs via the mouth is often changed to one that goes through an incision in the front of the windpipe (trachea) in the neck. This is called a tracheostomy. Tracheostomy is an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units.

At present we do not know if it is better to perform a tracheostomy in the early stages (first 4 days) of a patient's illness, or wait until 10 days or more. By doing the tracheostomy earlier, patients may recover faster, but by doing it later some patients may avoid the need for a tracheostomy altogether. Doctors really do not know which is best.

The Intensive Care Society, a professional body representing most of the doctors working in intensive care units, is trying to find the answer. It is conducting a national study involving over 1200 intensive care patients in many hospitals around the UK. This will compare the progress of the patients who receive "early" or "late" tracheostomy.

This study has been reviewed and approved by a Main Research Ethics Committee.

Why was I chosen and what happened to me?

At the time you entered the study your doctors believed that it was going to take 7 or more days before you were going to be able to breathe on your own without any help from a ventilator (breathing machine).

As we do not know whether it is better to perform a tracheostomy early or later in a patient's illness, we need to make comparisons. Patients are put into groups and then compared. The groups are selected by a computer that decides on a chance basis (as if it were tossing a coin) whether the patient should receive an "early" tracheostomy (within 4 days of admission to the intensive care unit), or a "late" tracheostomy after 10 days or more. In your case the decision on when to perform the tracheostomy was made this way. The local investigator [local consultants name here] will be able to tell you if you received an early tracheostomy, a late tracheostomy, or no tracheostomy at all.

We then collected some information about your treatment whilst you were on the Intensive Care Unit, and collected some personal identifying details to enable us to follow up your health status once you have left the unit.

What if something had gone wrong?

This study is investigating an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units. If you have been harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

What happens now?

Your remaining stay in hospital will continue as normal. There is no need for you to undergo any special tests or investigations or for you to be inconvenienced in any way.

Why are you explaining this to me?

As we enrolled you in a study whilst you were too ill to receive an explanation, it is important that we explain what the study involved now you are recovered.

What information has been/will be collected about me?

As part of the study routine information on your treatment was collected. If you do not wish for the data collected about your treatment to be used, this will be destroyed. Information in your hospital records remains unaffected. In addition, appropriate personal identifying details were collected to enable us to be kept informed about your health once you have left the Intensive Care Unit. It is possible that we will contact your GP to see how you are doing, or we may follow your health through a government agency called the Office of National Statistics which is told about all the births and deaths in the United Kingdom. If you decide not to allow us to follow up your health status, then we will abide by your wishes and not collect follow up data on you. You do not have to give a reason, and the standard of care you receive will not be affected.

Will my taking part be kept confidential?

All the information that has been collected about you during the course of the research study will be kept strictly confidential. Your identifying details will be held in a secure environment and only accessed by the research team for the purposes of follow up.

What will happen to the results of the research study?

The study is estimated to take just over three years and it is hoped that the results will be available on the Intensive Care Society's web page (www.ics.ac.uk) in 2008. If you would like a copy of the published results, please contact the Principal Local Investigator [local consultant and telephone number here] who is the consultant leading the study at the intensive care unit.

[On local hospital headed paper]

Centre No.

TracMan Study

PATIENT CONSENT TO CONTINUE FORM

Version 1 – 26 October 2007
MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

- | | | |
|---|---|----------------------|
| 1 | I confirm that I have read and understand the information sheet dated [date and version here] for the above study and have had the opportunity to ask questions | <input type="text"/> |
| 2 | I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected | <input type="text"/> |
| 3 | I understand that sections of any of my medical notes may be looked at by responsible individuals involved with the study. I give permission for these individuals to have access to my records | <input type="text"/> |
| 4 | I give permission for my personal identifying information to be collected, stored and used by the study office to enable follow up of my health status. This is on the understanding that any information will be treated with the strictest security and confidentiality | <input type="text"/> |
| 5 | I give permission for appropriate personal identifying information to be passed onto the Office of National Statistics for the purposes of following up my health status | <input type="text"/> |
| 6 | I give permission for my GP to be contacted about my health status | <input type="text"/> |
| 7 | I give permission for information about me to be gathered from the Office of National Statistics through the flagging system for follow up purposes | <input type="text"/> |
| 8 | I agree to take part in the above study | <input type="text"/> |

Name of patient	Date	Signature
Name of person taking consent (if not Principal Local Investigator)	Date	Signature
Name of Principal Local Investigator	Date	Signature

Photocopy x 2: 1 copy for patient, 1 copy for patients hospital notes, top copy for Principal Investigator's study file,


APPENDIX 7

CONSENT PROCESS AND DOCUMENTATION
FOR ADULTS IN THE INTENSIVE CARE UNIT
WHO DO **NOT** HAVE CAPACITY TO CONSENT

SCOTLAND

ADULTS WITH INCAPACITY
(SCOTLAND) ACT 2000

**Process for obtaining consent in Scotland:
Hospitals falling under the Adults with Incapacity (Scotland) Act 2000**

<p>Patient fulfils eligibility criteria but does not have capacity to consent to trial</p> <p>Has the patient a Welfare Guardian or Nearest Relative?</p>	
YES	NO
<p>Is this person willing and able to take on the responsibilities of Welfare Guardian/Nearest Relative (WG/NR) in this situation?</p> <p align="center">No </p> <p>If Yes</p> <ul style="list-style-type: none"> • Explanation to be given in person • Written consent to be signed by WG/NR • If WG/NR not present in person, verbal consent to be obtained by telephone using 'Welfare Guardian/Nearest Relative <i>Verbal Consent</i>' form. • Written consent to be obtained as soon as possible if practical • Local investigators will ensure that the WG/NR receives a copy of the consent form, and that a copy is placed in the patient's notes. The top copy consent form must be filed in the TracMan Binder 2 at the collaborating hospital. • If patient regains competence prior to/at ICU discharge, inform of participation, provide 'Patient Information Sheet' and obtain consent for use of information on 'Patient Consent following consent from Welfare Guardian/Nearest Relative' form • Local investigators will ensure that the patient receives a copy of the consent form, and that a copy is placed in the patient's notes. The top copy consent form must be filed in the TracMan Binder 2 at the collaborating hospital. 	<ul style="list-style-type: none"> • The patient cannot be entered into the trial

- If the patient refuses to **continue** in the trial (i.e.after randomisation), they are free to withdraw. Local investigators will ensure that the 'Withdrawal from trial' sheet in the Patient Data Booklet is completed and returned to the trial office.as soon as possible

*Under the English Mental Capacity Act 2005 a person **lacking capacity** is defined as:*

Someone unable

- *to understand information relevant to the decision*
- *to retain that information*
- *to use or weigh that information*
- *to communicate a decision*

and this is deemed to be situation specific

The High Court (England) held that an adult **has capacity** to consent if:

- he or she can understand and retain the information relevant to the decision in question
- believe that information
- weigh that information in the balance to arrive at a choice

The quality of consent should be ascertained from the responses given. Questions should be encouraged, and an opportunity to clarify information provided.

If a patient dies before regaining consciousness and the Welfare Guardian/Nearest Relative has given consent, the patient's data will be included in the study.

Documentation to use is detailed over the page.

[On local hospital headed paper]

Centre No.

TracMan Study

**COVERING STATEMENT FOR PATIENT'S WELFARE GUARDIAN/NEAREST RELATIVE
TO BE GIVEN THE PATIENT INFORMATION SHEET**

Version 8 - 20 September 2004

MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

We would like your relative to take part in a research study while he/she is a patient in this intensive care unit. Unfortunately, your relative is not well enough to be able to decide for him/herself whether or not to participate. Therefore as their welfare guardian/nearest relative, we ask you to read the Patient Information Sheet carefully and give your consent for your relative to take part in this medical research.

When your relative has regained consciousness and has the ability to understand the purpose of this study, we will explain the study to them and seek his/her permission to collect data for the study.

If you have further questions either now or at any time subsequently, please feel free to contact [name of consultant and telephone number], the consultant leading the study on this unit.

Thank you for your time in considering this request

Attached: Patient Information Sheet

[On local hospital headed paper]

Centre No.

TracMan Study

WELFARE GUARDIAN/NEAREST RELATIVE CONSENT

Version 8 – 20 September 2004
MainREC number: 04/MRE00/43

Regarding patient (please write patients **name** here): _____

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

- | | | |
|---|---|---|
| 1 | I confirm that I have read and understand the information sheet dated [date and version here] for the above study and have had the opportunity to ask questions | <div style="border: 1px solid black; width: 80px; height: 25px;"></div> |
| 2 | I give consent for my relative to participate in the study | <div style="border: 1px solid black; width: 80px; height: 25px;"></div> |
| 3 | I understand that sections of any of my relative’s medical notes may be looked at by responsible individuals involved with the study. I give permission for these individuals to have access to my relative’s records | <div style="border: 1px solid black; width: 80px; height: 25px;"></div> |
| 4 | I understand that personal identifying information will be collected, stored and used by the study office to enable follow up of my relative’s health status. This is on the understanding that any information will be treated with the strictest security and confidentiality | <div style="border: 1px solid black; width: 80px; height: 25px;"></div> |
| 5 | I give permission for my relative’s personal identifying information to be passed onto the Office of National Statistics for the purpose of following up their health status ... | <div style="border: 1px solid black; width: 80px; height: 25px;"></div> |
| 6 | I give permission for my relative’s GP to be contacted about their health status..... | <div style="border: 1px solid black; width: 80px; height: 25px;"></div> |
| 7 | I give permission for information about my relative to be gathered from the Office of National Statistics through the flagging system for follow up purposes | <div style="border: 1px solid black; width: 80px; height: 25px;"></div> |
| 8 | I am the patients (tick one box) : <input type="checkbox"/> nearest relative <input type="checkbox"/> welfare guardian | |

↓
If you answered ‘nearest relative’ to ‘8’ above, please indicate:

- (a) Your degree of kinship to the participant: _____
- (b) I confirm there is no nearer relative (tick box):
- (c) I confirm there is no welfare guardian (tick box):

Name of welfare guardian/nearest relative	Date	Signature
Name of person taking consent (if not Principal Local Investigator)	Date	Signature
Name of Principal Local Investigator	Date	Signature

Photocopy x 2: 1 copy for legal representative, 1 copy for patients hospital notes, top copy for Principal Investigator’s study file,

[On local hospital headed paper]

Centre No.

TracMan Study

**WELFARE GUARDIAN/NEAREST RELATIVE
VERBAL CONSENT FORM**

Version 8 – 20 September 2004
MainREC number: 04/MRE00/43

Use this form if consent from a relative has to be obtained verbally

Regarding patient (please write patients **name** here): _____

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

1 I confirm that the patient’s inclusion in the above study has been discussed with the welfare guardian/nearest relative and that they were offered the opportunity to ask questions/ask for clarification

2 I confirm he/she has given consent for the patient to be in the study. He/she understands that relevant sections of the patient’s notes may be looked at by responsible individuals involved with the study and does not object to these individuals having access to the patient’s records

3 I confirm he/she understands that personal identifying details will be collected for this patient and that he/she has given consent for this information to be collected, stored and used for follow up purposes

4 The person consenting is (tick one box): nearest relative welfare guardian

↓
If you answered ‘nearest relative’ to ‘4’ above, please indicate:

(a) Their degree of kinship to the participant: _____

(b) That they have confirmed there is no nearer relative (tick box):

(c) That they have confirmed there is no welfare guardian (tick box)

Please initial box

5 A copy of the Covering Statement and Patient Information Sheet has been given or sent to the welfare guardian/nearest relative (please tick as appropriate): Yes No

Name of welfare guardian/nearest relative Date Signature

Name of person informing welfare guardian/nearest relative Date Signature
(if not Principal Local Investigator)

Name of Principal Local Investigator Date Signature

Photocopy x 2: 1 copy for legal representative, 1 copy for patients hospital notes, top copy for Principal Investigator’s study file,

[On local hospital headed paper]

Centre No.

TracMan Study

**PATIENT INFORMATION SHEET:
CONSENT FROM PATIENT FOLLOWING WELFARE GUARDIAN/NEAREST RELATIVE CONSENT**

Version 9 - 6 March 2006
MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

During your stay in the intensive care unit you took part in a research study that is currently taking place in many intensive care units throughout the UK. It is important for you to understand why the research is being done and what it involves. Please read the following information carefully and, if you wish, discuss it with your welfare guardian/nearest relative or other family/friends. Ask if there is anything that is unclear or if you would like any more information. Thank you for reading this.

What is the purpose of the study?

Patients who need help with their breathing (artificial ventilation) have a tube placed through their mouths into their lungs. This tube is connected to the machine that assists their breathing.

If patients require assistance with their breathing for long periods of time, the tube that goes into the lungs via the mouth is often changed to one that goes through an incision in the front of the windpipe (trachea) in the neck. This is called a tracheostomy. Tracheostomy is an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units.

At present we do not know if it is better to perform a tracheostomy in the early stages (first 4 days) of a patient's illness, or wait until 10 days or more. By doing the tracheostomy earlier, patients may recover faster, but by doing it later some patients may avoid the need for a tracheostomy altogether. Doctors really do not know which is best.

The Intensive Care Society, a professional body representing most of the doctors working in Intensive Care Units, is trying to find the answer. It is conducting a national study involving over 1200 intensive care patients in many hospitals around the UK. This will compare the progress of patients who receive "early" or "late" tracheostomy.

This study has been reviewed and approved by a Main Research Ethics Committee.

Why was I chosen and what happened to me?

At the time you entered the study your doctors believed that it was going to take 7 or more days before you were going to be able to breathe on your own without any help from a ventilator (breathing machine).

As we do not know whether it is better to perform a tracheostomy early or later in a patient's illness, we need to make comparisons. Patients are put into groups and then compared. The groups are selected by a

computer that decides on a chance basis (as if it were tossing a coin) whether the patient should receive an "early" tracheostomy (within 4 days of admission to the Intensive Care Unit) or a "late" tracheostomy after 10 days or more. In your case the decision on when to perform the tracheostomy was made this way. The local investigator [local consultants name here] will be able to tell you if you received an early tracheostomy, a late tracheostomy, or no tracheostomy at all.

We then collected some information about your treatment whilst you were on the Intensive Care Unit, and we will record the date you leave hospital.

What if something had gone wrong?

This study is investigating an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units. If you have been harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

What happens now?

Your remaining stay in hospital will continue as normal. There is no need for you to undergo any special tests or investigations or for you to be inconvenienced in any way.

Why are you explaining this to me?

As part of the study routine information on your treatment was collected, along with some personal identifying details. We obtained consent to do this from your welfare guardian/nearest relative as you were too ill to receive an explanation. It is therefore important that we explain what the study involved now you are recovered. We are now seeking for your consent to continue to collect the data we require.

What information has been/will be collected about me?

Appropriate personal identifying details were collected to enable us to be kept informed about your health once you have left the Intensive Care Unit. It is possible that we will contact your GP to see how you are doing, or we may follow your health through a government agency called the Office of National Statistics which is told about all the births and deaths in the United Kingdom. If you decide not to allow us to follow up your health status, then we will abide by your wishes and not collect follow up data on you. You do not have to give a reason, and the standard of care you receive will not be affected.

Will my taking part be kept confidential?

All the information that has been collected about you during the course of the research study will be kept strictly confidential. Your identifying details will be held in a secure environment and only accessed by the research team for the purposes of follow up.

What will happen to the results of the research study?

The study is estimated to take just over three years and it is hoped that the results will be available on the Intensive Care Society's web page (www.ics.ac.uk) in 2008. If you would like a copy of the published results, please contact the Principal Local Investigator [local consultant and telephone number here] who is the consultant leading the study at the intensive care unit.

[On local hospital headed paper]

Centre No.

TracMan Study

**PATIENT CONSENT FOLLOWING
CONSENT FROM WELFARE GUARDIAN/NEAREST RELATIVE**

Version 8 – 20 September 2004
MainREC number: 04/MRE00/43

Regarding patient (please write patients name here): _____

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

- | | | |
|---|--|----------------------|
| 1 | I confirm that I have read and understand the information sheet [date and version here] for the above study and have had the opportunity to ask questions..... | <input type="text"/> |
| 2 | I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected..... | <input type="text"/> |
| 3 | I understand that sections of any of my medical notes may be looked at by responsible individuals involved with the study. I give permission for these individuals to have access to my records | <input type="text"/> |
| 4 | I give permission for personal identifying information to be collected, stored and used by the study office to enable follow up of my health status. This is on the understanding that any information will be treated with the strictest security and confidentiality | <input type="text"/> |
| 5 | I give permission for appropriate personal identifying information to be passed onto the Office of National Statistics for the purpose of following up my health status | <input type="text"/> |
| 6 | I give permission for my GP to be contacted about my health status | <input type="text"/> |
| 7 | I give permission for information about me to be gathered from the Office of National Statistics through the flagging system for follow up purposes | <input type="text"/> |
| 8 | I agree to take part in the above study | <input type="text"/> |

Name of Patient

Date

Signature

Name of person taking consent
(if not Principal Local Investigator)

Date

Signature

Name of Principal Local Investigator

Date

Signature

Photocopy x 2: 1 copy for legal representative, 1 copy for patients hospital notes, top copy for Principal Investigator's study file,

APPENDIX 8

CONSENT PROCESS AND DOCUMENTATION FOR ADULTS IN THE INTENSIVE CARE UNIT WHO DO **NOT HAVE CAPACITY TO CONSENT**

NORTHERN IRELAND

Once the Mental Capacity Act 2005 is implemented in Northern Ireland hospitals will follow the consent process for England and Wales.

Process for obtaining 'no objection' from relatives:
Hospitals in Northern Ireland

Once the Mental Capacity Act 2005 is implemented in Northern Ireland hospitals will follow the consent process for England and Wales.

Patient fulfils eligibility criteria but does not have capacity to consent to trial	
Does the patient have a relative?	
YES	NO
<ul style="list-style-type: none"> • Explanation to be given in person • Written 'no objection' to be signed by relative • If relative not present in person, verbal 'no objection' to be obtained by telephone using 'Verbal 'no objection' form • Written 'no objection' to be obtained as soon as possible if practical • Local investigators will ensure that the relative receives a copy of the consent form, and that a copy is placed in the patient's notes. The top copy consent form must be filed in the TracMan Binder 2 at the collaborating hospital. • If the relative refuses, the patient cannot go into the trial. The patient will receive the usual treatment as defined by the clinician responsible for the patient's care. • If patient regains competence prior to/at ICU discharge, inform of participation, provide 'Patient Information Sheet' and obtain retrospective consent for use of information on 'Patient Consent' form • Local investigators will ensure that the patient receives a copy of the consent form, and that a copy is placed in the patient's notes. The top copy consent form must be filed in the TracMan Binder 2 at the collaborating hospital. • If the patient refuses to consent after randomisation they are free to withdraw. Local investigators will 	<ul style="list-style-type: none"> • The patient cannot be entered into the trial

<p>ensure that the 'Withdrawal from trial' sheet in the Patient Data Booklet is completed and returned to the trial office as soon as possible</p>	
<p><i>Under the English Mental Capacity Act 2005 a person lacking capacity is defined as:</i> <i>Someone unable</i></p> <ul style="list-style-type: none"> • <i>to understand information relevant to the decision</i> • <i>to retain that information</i> • <i>to use or weigh that information</i> • <i>to communicate a decision</i> <p><i>and this is deemed to be situation specific</i></p> <p>The High Court (England) held that an adult has capacity to consent if:</p> <ul style="list-style-type: none"> • he or she can understand and retain the information relevant to the decision in question • believe that information • weigh that information in the balance to arrive at a choice <p>The quality of consent should be ascertained from the responses given. Questions should be encouraged, and an opportunity to clarify information provided.</p>	

If a patient dies before regaining consciousness and the relative has given 'no objection', the patient's data will be included in the study.

Documentation to use is detailed over the page.

[On local hospital headed paper]

Centre No.

TracMan Study

**COVERING STATEMENT FOR PATIENT'S RELATIVE
TO BE GIVEN THE PATIENT INFORMATION SHEET**

Version 8 - 20 September 2004
MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

We would like your relative to take part in a research study while he/she is a patient in this intensive care unit. Unfortunately, your relative is not well enough to be able to decide for him/herself whether or not to participate. Legally, you cannot provide consent on his/her behalf. However, we ask you to read the Patient Information Sheet carefully and give your opinion as to whether or not you think your relative would have objected to taking part in this medical research.

When your relative has regained consciousness and has the ability to understand the purpose of this study, we will explain the study to them and seek his/her permission to use the data we have collected retrospectively.

If you have further questions either now or at any time subsequently, please feel free to contact [name of consultant and telephone number], the consultant leading the study on this unit.

Thank you for your time in considering this request.

Attached: Patient Information Sheet

[On local hospital headed paper]

Centre No.

TracMan Study

‘NO OBJECTION’ FORM FOR RELATIVE

Version 8 – 20 September 2004
MainREC number: 04/MRE00/43

Regarding patient (please write patients name here): _____

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

- 1 I confirm that I have read and understand the information sheet dated [date and version here] for the above study and have had the opportunity to ask questions
- 2 I understand that I cannot legally give consent for my relative to participate in the study. However in my opinion, he/she would not have objected to taking part
- 3 I understand that sections of any of my relative’s medical notes may be looked at by responsible individuals involved with the study. I give permission for these individuals to have access to my relative’s records

The following asks you for permission to collect your relative’s personal identifying details. Once your relative regains the capacity to consent for themselves, they will be asked to confirm that they give permission for these details to be collected.

- 4 I understand that appropriate personal identifying information will be collected, stored and used by the study office to enable follow up of my relative’s health status. This is on the understanding that any information will be treated with the strictest security and confidentiality
- 5 I give permission for my relative’s personal identifying information to be passed onto the Office of National Statistics for the purpose of following up their health status
- 6 I give permission for my relative’s GP to be contacted about their health status
- 7 I give permission for information about my relative to be gathered from the Office of National Statistics through the flagging system for follow up purposes

8 I am the patients: _____
(please write your relationship to the patient here, for example wife/partner/brother etc)

Name of relative	Date	Signature
Name of person informing relative (if not Principal Local Investigator)	Date	Signature
Name of Principal Local Investigator	Date	Signature

Photocopy x 2: 1 copy for relative, 1 copy for patients hospital notes, top copy for Principal Investigator’s study file,

[On local hospital headed paper]

Centre No.

TracMan Study

'NO OBJECTION' FORM (VERBAL)

Use this form if assent from a relative has to be obtained verbally

Version 8 – 20 September 2004

MainREC number: 04/MRE00/43

Regarding patient (please write patients **name** here): _____

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

- | | | |
|---|---|----------------------|
| 1 | I confirm that the patient’s inclusion in the above study has been discussed with the appropriate relative and that they were offered the opportunity to ask questions/ask for clarification | <input type="text"/> |
| 2 | I confirm he/she has given verbal assent for the patient to be in the study. He/she understands that relevant sections of the patient’s notes may be looked at by responsible individuals involved with the study and does not object to these individuals having access to the patient’s records | <input type="text"/> |
| 3 | I confirm he/she understands that personal identifying details will be collected for this patient and that he/she does not object to this information being collected, stored and used for follow up purposes | <input type="text"/> |

Name of relative: _____

Relationship to patient: _____

Date and time relative was informed: Date: ____/____/____ Time: (24 hr clock) ____:____

Comments, including any objections: _____

Please initial box

- | | | | | |
|---|--|------------------------------|-----------------------------|----------------------|
| 4 | A copy of the Covering Statement and Patient Information Sheet has been given or sent to the patient’s relative (<i>please tick as appropriate</i>): | Yes <input type="checkbox"/> | No <input type="checkbox"/> | <input type="text"/> |
|---|--|------------------------------|-----------------------------|----------------------|

Name of person informing relative (if different from Principal Local Investigator)	Date	Signature
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Name of Principal Local Investigator	Date	Signature
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Photocopy x 2: 1 copy for relative, 1 copy for patients hospital notes, top copy for Principal Investigator’s study file,

[On local hospital headed paper]

Centre No.

TracMan Study

PATIENT INFORMATION SHEET: RETROSPECTIVE CONSENT FROM PATIENT**Version 9 - 6 March 2006**

MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of "early" or "late" tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

During your stay in the intensive care unit you took part in a research study that is currently taking place in many intensive care units throughout the UK. It is important for you to understand why the research is being done and what it involves. Please read the following information carefully and, if you wish, discuss it with your relatives or friends. Ask if there is anything that is unclear or if you would like any more information. Thank you for reading this.

What is the purpose of this study?

Patients who need help with their breathing (artificial ventilation) have a tube placed through their mouths into their lungs. This tube is connected to the machine that assists their breathing.

If patients require assistance with their breathing for long periods of time, the tube that goes into the lungs via the mouth is often changed to one that goes through an incision in the front of the windpipe (trachea) in the neck. This is called a tracheostomy. Tracheostomy is an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units.

At present we do not know if it is better to perform a tracheostomy in the early stages (first 4 days) of a patient's illness, or wait until 10 days or more. By doing the tracheostomy earlier, patients may recover faster, but by doing it later some patients may avoid the need for a tracheostomy altogether. Doctors really do not know which is best.

The Intensive Care Society, a professional body representing most of the doctors working in intensive care units, is trying to find the answer. It is conducting a national study involving over 1200 intensive care patients in many hospitals around the UK. This will compare the progress of the patients who receive "early" or "late" tracheostomy.

This study has been reviewed and approved by a Main Research Ethics Committee.

Why was I chosen and what happened to me?

At the time you entered the study your doctors believed that it was going to take 7 or more days before you were going to be able to breathe on your own without any help from a ventilator (breathing machine).

As we do not know whether it is better to perform a tracheostomy early or later in a patient's illness, we need to make comparisons. Patients are put into groups and then compared. The groups are selected by a computer that decides on a chance basis (as if it were tossing a coin) whether the patient should receive an "early" tracheostomy (within 4 days of admission to the intensive care unit), or a "late" tracheostomy after 10 days or more. In your case the decision on when to perform the tracheostomy was made this way. The local investigator [local consultants name here] will be able to tell you if you received an early tracheostomy, a late tracheostomy, or no tracheostomy at all.

We then collected some information about your treatment whilst you were on the Intensive Care Unit, and collected some personal identifying details to enable us to follow up your health status once you have left the unit.

What if something had gone wrong?

This study is investigating an established procedure rather than a new technique. Tracheostomies are used in virtually all intensive care units. If you have been harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

What happens now?

Your remaining stay in hospital will continue as normal. There is no need for you to undergo any special tests or investigations or for you to be inconvenienced in any way.

Why are you explaining this to me?

As we enrolled you in a study whilst you were too ill to receive an explanation, it is important that we explain what the study involved now you are recovered.

What information has been/will be collected about me?

As part of the study routine information on your treatment was collected. If you do not wish for the data collected about your treatment to be used, this will be destroyed. Information in your hospital records remains unaffected. In addition, appropriate personal identifying details were collected to enable us to be kept informed about your health once you have left the Intensive Care Unit. It is possible that we will contact your GP to see how you are doing, or we may follow your health through a government agency called the Office of National Statistics which is told about all the births and deaths in the United Kingdom. If you decide not to allow us to follow up your health status, then we will abide by your wishes and not collect follow up data on you. You do not have to give a reason, and the standard of care you receive will not be affected.

Will my taking part be kept confidential?

All the information that has been collected about you during the course of the research study will be kept strictly confidential. Your identifying details will be held in a secure environment and only accessed by the research team for the purposes of follow up.

What will happen to the results of the research study?

The study is estimated to take just over three years and it is hoped that the results will be available on the Intensive Care Society's web page (www.ics.ac.uk) in 2008. If you would like a copy of the published results, please contact the Principal Local Investigator [local consultant and telephone number here] who is the consultant leading the study at the intensive care unit.

[On local hospital headed paper]

Centre No.

TracMan Study

PATIENT CONSENT FORM

Version 8 – 20 September 2004
MainREC number: 04/MRE00/43

Title of project: A study to investigate whether the use of “early” or “late” tracheostomy is of benefit to patients in intensive care.

Principal Local Investigator: [name and telephone number here]

Please initial boxes

- 1 I confirm that I have read and understand the information sheet dated [date and version here] for the above study and have had the opportunity to ask questions
- 2 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected
- 3 I understand that sections of any of my medical notes may be looked at by responsible individuals involved with the study. I give permission for these individuals to have access to my records
- 4 I give permission for my personal identifying information to be collected, stored and used by the study office to enable follow up of my health status. This is on the understanding that any information will be treated with the strictest security and confidentiality
- 5 I give permission for appropriate personal identifying information to be passed onto the Office of National Statistics for the purposes of following up my health status
- 6 I give permission for my GP to be contacted about my health status
- 7 I give permission for information about me to be gathered from the Office of National Statistics through the flagging system for follow up purposes
- 8 I agree to take part in the above study

Name of patient	Date	Signature
Name of person taking consent (if not Principal Local Investigator)	Date	Signature
Name of Principal Local Investigator	Date	Signature

Photocopy x 2: 1 copy for patient, 1 copy for patients hospital notes, top copy for Principal Investigator's study file,

PATIENTS NOT RANDOMISED TO THE TRACMAN TRIAL: PATIENT SCREENING LOG

Centre number:

Centre name:

Please record the details of all patients who were assessed on Day 1-4, but not randomised to the TracMan Trial. This information is required to meet the CONSORT trial reporting guidelines.

Today's date	Patient's Initials	Date of birth	Sex (M/F)	Did the patient receive a tracheostomy? (tick one)		The patient was not randomised to TracMan because:				
				Yes	No	A Consultant CERTAIN about tracheostomy timing	B Can't facilitate tracheostomy by day 4	C Excluding according to general Exclusion Criteria	D Excluded as patient/relative refused to take part (tick if applies)	E Other reason (please document reason below):

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 University College London Hospitals
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 Chief Investigator
 TracMan Trial

DATA MONITORING AND ETHICS COMMITTEE

Senior Trialist (Chair): Professor Peter Sandercock

Senior Clinician: Professor Monty Mythen

Independent Statistician: Mrs Sue Richards

TRACMAN TRIAL – TRIAL OFFICE TEAM CONTACT DETAILS

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