Frequently Asked Questions (FAQs)

1 General recruitment questions

Q: Our ICU only does tracheostomies during the week, what do we need to consider before randomising a patient?
A: To be eligible for the trial a patient must be able to have a tracheostomy within four days of *admission* to the ICU, *not* four *working* days. You should not recruit patients you know cannot receive a tracheostomy in this window.

Q: Our ICU only does tracheostomies during the week. How does this impact on recruitment?
A: You should only recruit patients who can receive a tracheostomy in your hospital within four days of *admission* to the ICU. In practice this means patients admitted on a Wednesday or Thursday must receive a tracheostomy by Friday if they are allocated to the early group. Similarly patients admitted on a Friday who are allocated to the early group will need to have a tracheostomy performed on the following Monday.

Q: What if, at the point of randomisation, I believe we can carry out the tracheostomy by day four. However after being randomised to 'early' tracheostomy an unexpected practical difficulty arises which makes it impossible to perform the tracheostomy by day four. What do I do?
A: The patient remains in the trial and you should carry out the tracheostomy at the earliest available opportunity. The trial tracheostomy procedure related data sheets will ask you to record what led to the delay.

Q: What if a patient is ventilated for a period in theatre recovery and then comes to the ICU?
A: The trial four day recruitment period starts when the patient arrives in ICU. (The trial's Patient Data Booklet will record the date ventilation started and whether this was in your ICU, or before admission to ICU.)

Q: What if my patient is too sick to do a tracheostomy safely today?
A: A patient should not be considered for the trial if they are too sick to have a tracheostomy. Review the patient daily for the first four days and randomise them only when they are stable enough to do a tracheostomy.

<u>Mixed HDU/ICU Units</u>

Q: If a patient is admitted to the ICU for Level 2 (HDU) care but is subsequently intubated, when does the trial four day recruitment period start?
A: For this type of patient the clock starts as they arrive in the ICU, not when their treatment has escalated to Level 3 care.

Q: Why do you start the clock on a Level 2 patient when they arrive in ICU, not when their care escalates to Level 3?
A: The time of the change-over from Level 2 to Level 3 is often poorly defined and the patients can escalate from Level 2 to Level 3 for non respiratory reasons.

Q: What if we plan to do a tracheostomy on a patient who is not intubated?
A: The patient is not eligible for the trial. This scenario is so rare that making special provision for these patients in the protocol causes unnecessary problems without increasing the recruitment rate.

2 The trial Inclusion Criteria

Q: In the trial Inclusion Criteria, what do you mean there is a "high chance" that the patient will require a further 7 days or more of ventilatory support during their ICU stay?
A: We would ask you to use your clinical judgement as you would in your day-to-day practice when predicting duration of ventilation.

Q: What if the opinions vary among consultant about what constitutes "too sick" for a tracheostomy?
A: The final decision rests with the consultant in overall charge of the ICU on that day.

Q: What do you mean by type 1 and type 2 respiratory failure?
A: These two broad definitions cover all types of respiratory failure.

Q: So what is type 1 respiratory failure?
A: This is where a patient is hypoxaemic or requires additional oxygen to maintain a normal blood oxygen tension. For example: pneumonia or ARDS.

Q: So what is type 2 respiratory failure?
A: This is where a patient is primarily hypercarbic (high arterial PCO_2). For example: COPD, hypoventilation due to acute neurological causes such as head injury.

3 The trial Exclusion Criteria:

<u>Clinical questions</u>

Q: What cut offs for oxygenation and clotting would you recommend to identify patients who are unsafe for a tracheostomy?
A: The trial doesn't dictate these, use existing local criteria if you have them or clinical judgement.

Q: The Exclusion Criteria includes "chronic hyperbaric (type 2) respiratory failure due to chronic neurological disease". Does this include COPD patients?
A: No. COPD patients suffer from a chronic respiratory (not a neurological) disease. Examples of patients who would be excluded are patients with chronic high cervical cord lesions or motor neurone disease.

General questions

Q: What if my patient has been transferred from another *hospital* but was *not* in their ICU, can I recruit them?
A: Yes, we only exclude ICU to ICU transfers.

Q: My patient has been transferred from an *ICU* in another hospital to this ICU, but their total ICU stay is under four days, can I recruit them?
A: No, this is a trial exclusion criterion.

Q: Which patients do we record on the Patient Screening Log?
A: If you answered 'yes' to the **first 3 questions** of the flowchart on the front of the Patient Recruitment Pack envelope, but did not go on to randomise the patient (for whatever reason), these patients should be placed on the Patient Screening Log.

4 Consent

Consent issues prior to randomisation

Q: Who can consent patients to the trial?
A: Any of the ICU consultants or an individual with appropriate experience that he or she nominates.

Q: What if we cannot contact any relative/next of kin to gain consent/'no objection'?
A: Do not recruit the patient.

Q: Who can sign the consent/'no objection' form?
A: A 'relative' can sign the consent form. 'Relative' means a person best able to give an opinion as to whether the patient would have consented to take part in the study had she or he been competent. In practice, this is usually the patients partner or near blood relative.

Q: Do we need to go through the NHS consent procedure as well as the trial consent procedure?
A: Yes. When any patient is having a procedure in an NHS hospital, the relevant consent procedures must be followed (in addition to trial consent).

Q: When we are consenting patients for the trial do we need to give a specific figure for complications or mortality?
A: No. If you give these figures as part of your standard NHS consent you should continue to do so. You should not change your practice because the trial is taking place.

Consent issues after randomisation

Q: Do I need to obtain *signed* consent following *verbal* consent/'no objection'?
A: You should make every effort to obtain signed consent following verbal consent/'no objection'. However if there are real practical impediments to obtaining signed consent/'no objection' the verbal consent may stand. You should record efforts made to contact the relative for signed consent/'no objection in the patient's notes.

Q: What happens if a patient in the *late* group regains capacity to consent (i.e. is both conscious *and* able to make informed decisions) prior to the late tracheostomy?
A: You should explain the trial to them and that their relative gave permission to include them. Ask whether they are happy to continue, and if they are, ask them to sign a **retrospective** consent form.

Q: What happens if a patient regains the capacity to consent (i.e. is both conscious *and* able to make informed decisions) prior to/at ICU discharge?
A: You should explain the trial to them and that their relative gave permission to include them. Ask whether they are happy to continue, and if they are, ask them to sign a **retrospective** consent form.

Q: What if the patient refuses to continue to take part in the trial following the relatives 'no objection'?
A: The patient's wishes must be respected at all times and they may withdraw from the trial if they so wish. Whilst they are under no obligation to give a reason for their withdrawal, the term "I don't want to take part" may mean many things in practice. It may therefore be helpful to clarify this statement with the patient and then record the outcome on page 25 of the Patient Data Booklet. Some possible examples of what the patient may mean by "I don't want to take part" are given below:

Q: Is the patient refusing to allow the trial to collect their *ICU data*?
A: A patient who refuses to allow their ICU data to be used for the trial should be recorded as 'Withdrawn permission to use ICU data' and *not* 'withdrawn from trial'. You may still collect the following three items of follow up data given below with their permission. If they give permission, the patient should sign the Consent Form, initialling all points except point 3:

a) Health Status at day 30 post randomisation (alive/dead)
b) Health Status at discharge from hospital (alive/dead)
c) Length of hospital stay.

Collection of this information does not involve the patient directly, but would be collected from the hospital records.

Q: Is the patient refusing to allow the trial to collect *follow up* data on them?
A: A patient who refuses to allow follow up data to be collected is 'withdrawn permission to collect follow up data' and *not* 'withdrawn from trial'. When signing the consent form they should be asked to initial points 1 to 3 and point 8, leaving out points 5, 6 and 7. The trial will not collect their follow up data.

Q: Is the patient refusing to allow the trial to collect any data on them (both *ICU* and *follow up*)?
A: A patient who refuses to allow both sets of data to be collected is 'withdrawn from trial'.

Q: What do I need to do about consent if my patient dies before being able to give his/her own consent following relative 'no objection'?
A: In this case a 'no objection' from the relative is the only 'permission' the trial needs to use that patient's data.

Q: Do I need to follow up patients who did not have the capacity to consent at ICU discharge?

A: No, the patient is physically in the trial from ICU admission to ICU discharge and the consent status at ICU discharge stands.

5 Tracheostomy

Q: Does it matter whether we do a surgical or percutaneous tracheostomy on an individual patient?
A: No, use whatever is clinically indicated.

Q: Does it matter which percutaneous technique we use on an individual patient?
A: No, use whatever is clinically indicated.

Q: Do we have to use a bronchoscope as part of our procedure?
A: Use or otherwise of a bronchoscope is a local decision, not part of the trial protocol.

<u>Questions – the 'early' group (tracheostomy on Day 1 to 4)</u>

Q: What if at the point of randomisation I believe we can carry out the tracheostomy by day four. However after being randomised to 'early' tracheostomy an unexpected practical difficulty arises which makes it impossible to perform the tracheostomy by day four. What do I do?
A: The patient remains in the trial and you should carry out the tracheostomy at the earliest available opportunity.

Q: What if my patient was randomised to the 'early' group but my considered clinical judgement suggests I should perform a tracheostomy *later* than the trial dictates?
A: When you recruited this patient to the trial, it was on the basis that you were uncertain whether early or late tracheostomy was in their best interests. There are very few circumstances where the patient's subsequent clinical course will introduce such a level of certainty that it is appropriate to violate the trial protocol. We would therefore expect the random allocation to be complied with except in extreme circumstances.

Questions – the ‘late’ group (no tracheostomy before Day 10)

Q: What if my patient was randomised to the ‘late’ group but my considered clinical judgement suggests I should perform a tracheostomy *earlier* than the trial dictates?
A: When you recruited this patient to the trial, it was on the basis that you were uncertain whether early or late tracheostomy was in their best interests. There are very few circumstances where the patient’s subsequent clinical course will introduce such a level of certainty that it is appropriate to violate the trial protocol. We would therefore expect the random allocation to be complied with except in extreme circumstances.

Q: On day ten it is clear my patient does not need a tracheostomy, do I have to perform one?
A: No, a tracheostomy is only required if it is clinically indicated. However your patient can receive a tracheostomy any time after day ten, so if the patient deteriorated a tracheostomy could be considered later (during the same ICU admission only).

Q: My patient has been extubated before day ten, what do I do about the tracheostomy?
A: Clearly the patient doesn’t need a tracheostomy, and you should record this fact on the ‘Late’ Tracheostomy – Procedure Related Data’ sheet in the Patient Data Booklet.

Q: My patient is randomised to receive a *late* tracheostomy but on day ten s/he has deteriorated and it is not safe to do the procedure, what do I do?
A: The late group can receive a tracheostomy on day ten or anytime after, but only if it is safe and a tracheostomy is still clinically indicated.

Q: My patient was allocated to receive a *late* tracheostomy, but day ten falls on a Saturday and our ICU does not do tracheostomies at a weekend. What do I do?
A: The patient in the late group can have a tracheostomy on or after day ten so delaying until a suitable working day is not a problem.

Q What do we do about a patient randomised in our ICU to 'late' tracheostomy, then before day 10 the patient is transferred to another ICU caring for L3 patients?
A: Inform the receiving ICU that the patient is in the TracMan trial and was allocated to 'late' tracheostomy; to have a tracheostomy on or after day 10. If the receiving hospital/consultant felt able to abide by the 'late' allocation [i.e. not give a tracheostomy until day 10], then this would be ideal. However as the patient is now under their clinical care, the trial has no right to expect the receiving consultant to abide by the allocation and leaves all decisions to the receiving professionals (as would be the case in standard practice).

6 Data collection

Admission Data – First 24 Hours Sheet

Q: When filling in the 'Admission Data – First 24 hours' sheet, where do I get the patient's Case Mix Programme Admission Number' from?
A: If your ICU takes part in the ICNARC Case Mix Programme you will be recording the 'CMP admission number' as part of your CMP dataset. It will be on the computer that is used to collect this data in your ICU.

Daily Data Collection Sheet

Q You are collecting 'date first ventilated' on page 7 of the Patient Data Booklet, but I can't see 'date last ventilated' being collected?

A: The daily data collection on page 11 of the Patient Data Booklet (PDB) asks collaborators to record what respiratory support the patient is receiving daily. As it is difficult to define ventilation (for example would 1 hour of post extubation non-invasive pressure support count as "ventilation"?) we are recording "Advanced respiratory support" rather than ventilation *per se*. "Advanced respiratory support" has a standard definition that is used country wide. The last date 'Advanced respiratory support' is indicated on the PDB will count as date last ventilated.

Q: When filling in the 'Daily Data Collection' sheet, what if the patient stays more than 19 days? I will need more forms.
A: Freestanding 'Daily Data Collection' forms are available from the TracMan Trial Binder 1 on your ICU.

Q: What if the patient is taking oral antibiotics, do I record this as antimicrobial use?
A: No, we are only recording intravenous antimicrobial use.

Q: My patient is receiving erythromycin to promote gut motility. Does this count as antimicrobial use in the daily data collection form?
A: No, erythromycin is given orally to promote gut motility and we are only collecting intravenous antimicrobial use.

Q: My patient is receiving temazepam as night sedation. Does this count as sedative use in the daily data collection form?
A: No, we are only collecting information on intravenous sedative use.

Q: My patient is receiving a morphine infusion as part of their sedative treatment. Does this count as sedative use?
A: Yes, if the morphine is being used as a sedative as well as an analgesic you should record a 'yes' in the sedative use box.

Q: My patient is on a PCA pump for analgesia following surgery, but is awake and breathing spontaneously, should I record the morphine used in the pump as a sedative?
A: No, this patient is receiving morphine for analgesia only.

Q: Should I include the anaesthetic drugs administered during the tracheostomy procedure as sedatives in the daily data collection form?
A: Yes.

Tracheostomy procedure-related data sheet

Q: We would like to have seen stenosis and other tracheostomy complications collected, why aren't they?

A: The trial is designed to detect a mortality difference, not a difference in complications. Data on immediate complications (procedure related), are collected. Without imaging or pulmonary function tests it is very difficult to both detect and hence accurately assess the incidence and severity of stenotic complications.

Serious, Unanticipated, Adverse Event Sheet

Q: What is a serious, unanticipated, adverse event?
A: This is something that occurs that you would not expect to occur during your normal practice of placing tracheostomies.

Q: When do I fill in the serious, unanticipated, adverse event form?
A: When you have an adverse event that you would not expect, **or**, if the patient dies as a result of the tracheostomy procedure or suffers a complication likely to lead to long term disability.

Q: We know three patients out of every thousand die as a direct result of performing a tracheostomy (see page 46 of Protocol), why do we need to record deaths on the '*unanticipated*' adverse event sheet?
A: The regulatory authorities that govern clinical trials require us to record procedure related deaths.

Q: What do I do with a serious, unanticipated, adverse event sheet after I have filled it in?
A: Please fax this sheet to us within three days of the event. Details are given in the Patient Data Booklet (page 23).

ICU Discharge Sheet

Q A patient had his tracheostomy changed for a mini-trach. Do you want the date of removal of *tracheostomy tube* or date *mini-trach removed*?

A: Date tracheostomy tube removed please.

Hospital Discharge Sheet

Q For patients discharged from ICU with tracheostomy in place, are you collecting date tracheostomy removed?

A: Yes, the *Hospital* Discharge Form will collect data for the period from ICU discharge to hospital discharge and one of the questions will be date tracheostomy removed. The Hospital Discharge Form is not in the Patient Data Booklet as it is only sent out for survivors. This will be sent to collaborators a few months after discharge from ICU.

7 Source data verification and monitoring

Q: What data verification is TracMan carrying out?

A: The primary outcome measure for the trial (patient status at 30 days post-randomisation), is being verified via the Office of National Statistics. (TracMan is carrying out the same level of source data verification as used in the PAC-Man Trial). A risk assessment was carried out:

Q: Do you carry out do primary source data verification on the *primary* outcome?

A: Yes. The primary outcome for the TracMan trial is a simple, straightforward outcome, mortality 30 days after randomization, i.e. “Is the patient alive or dead on day 30 following randomization”. The response from the ICU and/or Hospital Discharge Sheet will be checked against patients alive/dead as reported to the trial office by the Office of National Statistics (ONS) Database and discrepancies investigated. This monitoring of the primary outcome measure was as directed by the Data Monitoring and Ethics Committee for the TracMan Trial.

Q: Do you carry out primary source data verification on the secondary outcomes?

A: For some of these yes, for others the Risk Assessment carried out showed that the potential hazard to the trial of not having primary source data verification was minimal, for full details see below.

(a) Mortality rate at (first) discharge from ICU and at discharge from hospital.
The response on the ICU and/or Hospital Discharge Sheet will be checked against patients alive/dead as reported to the trial office by the Office of

National Statistics (ONS) Database and discrepancies investigated. Date of death is provided.

(b) ICU/Hospital length of stay.
No source data verification of this outcome will take place. The risk to the trial that these dates will be systematically recorded incorrectly solely in the early or late group (across the 1,208 sample size), is low.

(c) Number of days receiving sedative medication.
No source data verification of this outcome will take place. The risk to the trial that this information will be systematically recorded incorrectly solely in the early or late group (across the 1,208 sample size), is low.

(d) Number of antibiotic-free days.
No source data verification of this outcome will take place. The risk to the trial that this information will be systematically recorded incorrectly in solely the early or late group (across the 1,208 sample size), is low.

TracMan is carrying out the same level of primary source data verification as used in the PAC-Man Trial.

Q: What about monitoring consent?

A: The trial monitors consent status at two points in time. (1) at randomisation (via the randomisation service), and (2) at the last point the patient is physically in the trial (at ICU discharge on the ICU Discharge Sheet in the Patient Data Booklet).

It is a condition of collaboration that Consultants agree to abide by the Protocol. It is therefore the collaborating consultant's responsibility to ensure the consent process for the trial is followed. The guidance on the consent/'no objection' forms indicate that the Principal Investigator (PI) must **co**-sign all consent forms and keep the trial copy. A 'Binder 2' was provided with your TracMan documentation to retain the PIs copy of the signed consent/'no objection' forms. Your local Trust Research and Development Office may visit to audit that the consent process for TracMan is being followed.

Q: What about monitoring the general quality of the research at participating sites?

A: As stated in the Research Governance Framework for Health and Social Care (2001/revised 2005), it is the Principal Investigators responsibility to monitor/audit research activity locally to ensure it is carried out in accordance with the Protocol. In addition, the responsibility to ensure that the trial is carried out according to Good Clinical Practice at the collaborating site for the TracMan trial has been delegated to the Principle Investigator via the Allocation of Responsibilities Agreement developed by the Sponsor of the trial.