

# TracMan Trial: Summary Protocol



## 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.

## The intervention

This trial is not introducing a new procedure but will be evaluating the timing of tracheostomy. Specifically: “Early” tracheostomy performed on day 1-4 post admission to ICU, compared with “Late” tracheostomy: performed after day 10 post admission to ICU.

## The setting

Adult ICUs in the NHS and private sector in the United Kingdom able to care for Level 3 patients.

## 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 (acute hospitals) Mortality rate at (first) discharge from ICU Number of days receiving any sedative medication Number of antibiotic-free days.

## Trial design

A multicentre, unblinded, randomised controlled clinical trial. This 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.

## Population to be studied

Patients receiving artificial ventilation who would be 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.

## Patient eligibility

### *Inclusion criteria:*

On days 1 to 4 following ICU admission, the primary caring ICU clinician will 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.

A patient may be deemed suitable for the study according to the uncertainty principal. 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 patient information and consenting procedures).

### *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.
- refusing consent or patients in whom relatives refuse assent.
- who were 'legally incompetent' prior to their hospital admission.
- or their relatives who do not understand written or verbal information for whom an interpreter is not available.
- Transferred to your ICU from another ICU

### **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.

### **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).

### **Sample size**

1692 patients (846 in each arm).

### **Planned recruitment period**

Recruitment will continue until 31st December 2008.

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**NB: Full Protocol available on TracMan website: <http://www.tracman.org.uk/>**