

# Tracheostomy Management in Critical Care

<b>Submission date</b> 25/11/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/12/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/06/2020	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
MRC ref: G0500970; 04/MRE00/43

## Study information

**Scientific Title**  
Tracheostomy Management in Critical Care: a randomised controlled trial

**Acronym**  
TracMan

## **Study objectives**

Patients with type 1 or type 2 respiratory failure requiring ventilation in the Intensive Care Unit (ICU). Investigating the best time to place a tracheostomy in such patients.

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.

Protocol can be found at: <http://www.tracman.org.uk/>

Please note that some information on this ISRCTN record have been amended as of 27/03/2009. The amendments include the following:

1. Scientific title was added
2. The anticipated end date has been updated from 31/12/2009 to 31/12/2008

Other changes are recorded in the relevant fields.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Scotland MREC A & Southampton and South West Hampshire REC A, approved in August 2004 (ref: 04/MRE00/43).

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Tracheostomy

## **Interventions**

Group 1: 'Early tracheostomy'  
Tracheostomy on day 1 to 4 post ICU admission

Group 2: 'Late tracheostomy'  
No tracheostomy before day 10 post ICU admission

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Mortality 30 days after randomisation.

### **Key secondary outcome(s)**

1. Mortality rate at discharge from hospital
2. ICU length of stay
3. Hospital length of stay (acute hospitals)
4. Mortality rate at (first) discharge from ICU
5. Number of days receiving any sedative medication
6. Number of antibiotic-free days

Added as of 27/03/2009:

Mortality is followed up for 2 years post randomisation.

All other secondary outcomes: data are collected whilst in intensive care, or up to hospital discharge

### **Completion date**

31/12/2008

## **Eligibility**

### **Key inclusion criteria**

Eligible patients are those who

1. Are intubated
2. Have a high chance of requiring a further 7 days or more of ventilatory support during their ICU stay
3. Have been in the intensive care unit for less than 4 days
4. The recruiting consultant is uncertain about whether an 'early' or 'late' tracheostomy is more appropriate for this patient

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key 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:

1. Not assessed on days 1-4 following ICU admission regarding their predicted requirement for at least a further 7 days of ventilatory support.
2. For whom an immediate tracheostomy is required to alleviate upper airway obstruction
3. With a tracheal stoma or tracheostomy tube in situ on admission to the ICU
4. With chronic hypercarbic (type 2) respiratory failure due to a chronic neurological disease

5. Less than 16 years of age
6. Previously enrolled in the TracMan trial during the same hospital admission
7. Refusing consent or patients in whom relatives refuse assent
8. Who were legally incompetent prior to their hospital admission
9. Or their relatives who do not understand written or verbal information for whom an interpreter is not available

**Date of first enrolment**

01/10/2004

**Date of final enrolment**

31/12/2008

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

c/o Lesley Morgan

Oxford

United Kingdom

OX3 9DU

## Sponsor information

**Organisation**

Oxford Radcliffe Hospitals NHS Trust (UK)

**ROR**

<https://ror.org/03h2bh287>

## Funder(s)

**Funder type**

Charity

**Funder Name**

The Intensive Care Society (UK) - funded the trial from 2004 to end of March 2006

## Funder Name

Medical Research Council (UK) (ref: G0500970) - funded the trial from 1st April 2006 until completion of the trial

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	22/05/2013		Yes	No
<a href="#">Results article</a>	propensity score matched cohort study results	01/06/2020	10/06/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes