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Tracheostomy Management in Critical Care

Submission date 25/11/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/12/2004	**Overall study status** Completed	
Last Edited 10/06/2020	**Condition category** Respiratory	

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?
Results article	results	22/05/2013		Yes	No
Results article	propensity score matched cohort study results	01/06/2020	10/06/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes