

Tracheostomy Management in Critical Care

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

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.tracman.org.uk/>

Contact information

Type(s)

Scientific

Contact name

Dr Duncan Young

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Multi-centre

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

Mortality 30 days after randomisation.

Secondary outcome measures

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

Overall study start date

01/10/2004

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

Age group

Adult

Sex

Both

Target number of participants

1,208

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

England

United Kingdom

Study participating centre

c/o Lesley Morgan

Oxford

United Kingdom

OX3 9DU

Sponsor information

Organisation

Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details

Research and Development Office

Manor House

John Radcliffe Hospital

Oxford

England

United Kingdom

OX3 9DU

Sponsor type

Hospital/treatment centre

Website

<http://www.oxfordradcliffe.nhs.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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