TracMan Presentation for Potential Collaborators

The ICS Trials Group

The Current Evidence for Tracheostomy Timing

Meta-analysis BMJ 2005;330:1243

- This publication arose from the systematic review of the literature we undertook before launching TracMan.
- The data in the paper were used to support the approach to the Intensive Care Society for funding.

  Studies included:
  - Randomised and quasi-randomised controlled trials that compared early tracheostomy with either late tracheostomy or prolonged endotracheal intubation.
- Early tracheostomy seemed to alter duration of ventilation and length of stay, but not mortality or incidence of VAP.

- Should we not accept this and not do the TracMan trial?

- The answer is an emphatic "**no**", the trial needs to go ahead. The findings are enough to warrant a UK trial, but the evidence is a long way from proof that tracheostomy *is* beneficial in UK ICUs.

- The shortened "ICU length of stay" finding depended on two American Studies. None of the other studies we found looked at length of stay.

- The American studies were vague about how they handled data from patients who died, and they looked at patients who were in service-specific ICUs, not the UK-type of mixed ICU.

- Only 226 patients in total were in the American studies, a relatively small number.

- To prove that early tracheostomy is (or is not) beneficial in UK ICUs we need a large randomised controlled trial……hence TracMan!

Tracheostomy Management in Critical Care

The ICS Trials Group

TracMan Trial

- Tracheostomy Management in Critical Care
- A UK, multicentre, randomised controlled trial (RCT)
- 53 ICUs (+ 8 waiting to join)
- ICUs able to care for Level 3 patients
- Funded by Intensive Care Society/Medical Research Council

TracMan History

- The TracMan Trial was established as a result of the Intensive Care Society's Priority-Setting Exercise in 2004
- The ICS membership were invited to put forward research questions that could be evaluated within a randomised controlled trial
- The membership were then invited to score those most frequently suggested questions
- Tracheostomy timing had the highest score and the TracMan Protocol was developed.

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.

Groups

“Early” tracheostomy:
Tracheostomy to be performed on day 1-4 post admission to ICU

Compared with

“Late” tracheostomy:
No tracheostomy before day 10 post admission to ICU

Day 1-4

- Day 1 time frame starts from time/day admitted to ICU, **not** first day intubated

Outcome Measures

Primary:

- Mortality 30 days after randomisation

Secondary:

- Mortality rate at discharge from ICU/Hospital
- Length of stay in ICU/Hospital
- Number of days receiving sedative medication
- Number of antibiotic-free days

Patient Group

Level 3 ICU Population

↓

Eligible Patients

↓

Inclusion Criteria

↓

Exclusion Criteria

↓

Randomised Patients

Patient Group

Level 3 ICU Population

↓

Eligible Patients

↓

Inclusion Criteria

↓

Exclusion Criteria

↓

Randomised Patients

Eligible Patients

- Intubated with endotracheal tube
- High chance will require 7 days or more of ventilatory support
- On ICU less than 4 days

Patient Group

Level 3 ICU Population

↓

Eligible Patients

↓

Inclusion Criteria

↓

Exclusion Criteria

↓

Randomised Patients

Inclusion Criteria

Consultant ‘uncertain’ early or late tracheostomy is more appropriate for this patient.

Patient Group

Level 3 ICU Population

↓

Eligible Patients

↓

Inclusion Criteria

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Exclusion Criteria

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Randomised Patients

Exclusion Criteria

Patients:

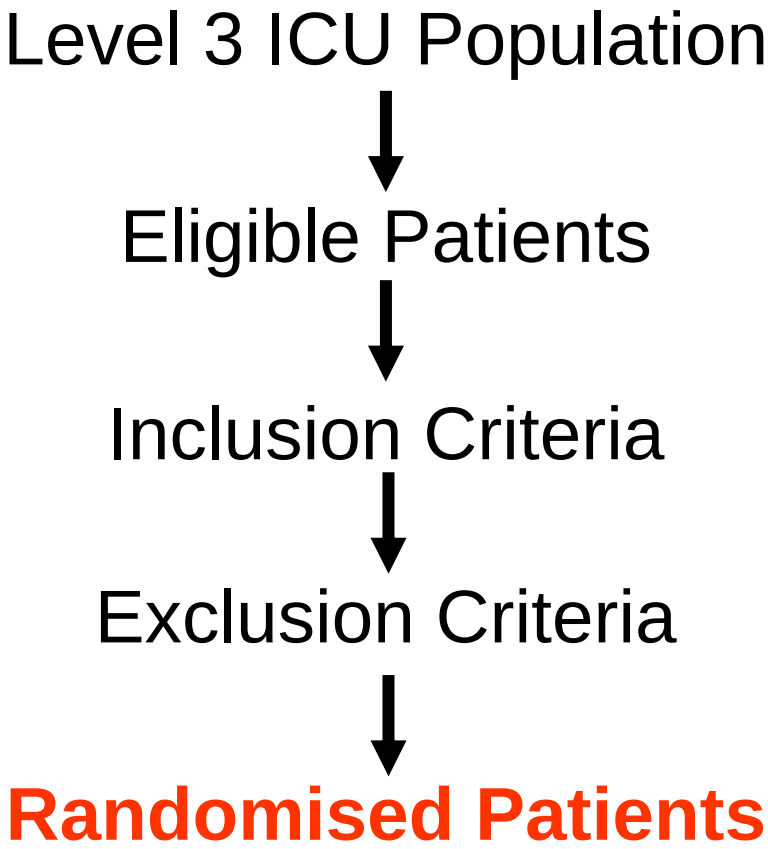
- not assessed on days 1-4
- for whom an immediate tracheostomy is required
- with a tracheal stoma or tracheostomy tube in situ on admission to the ICU
- with chronic hypercarbic (type 2) respiratory failure due to a chronic neurological disease
- less than 16 years of age
- previously enrolled in the 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

Patients not in the trial

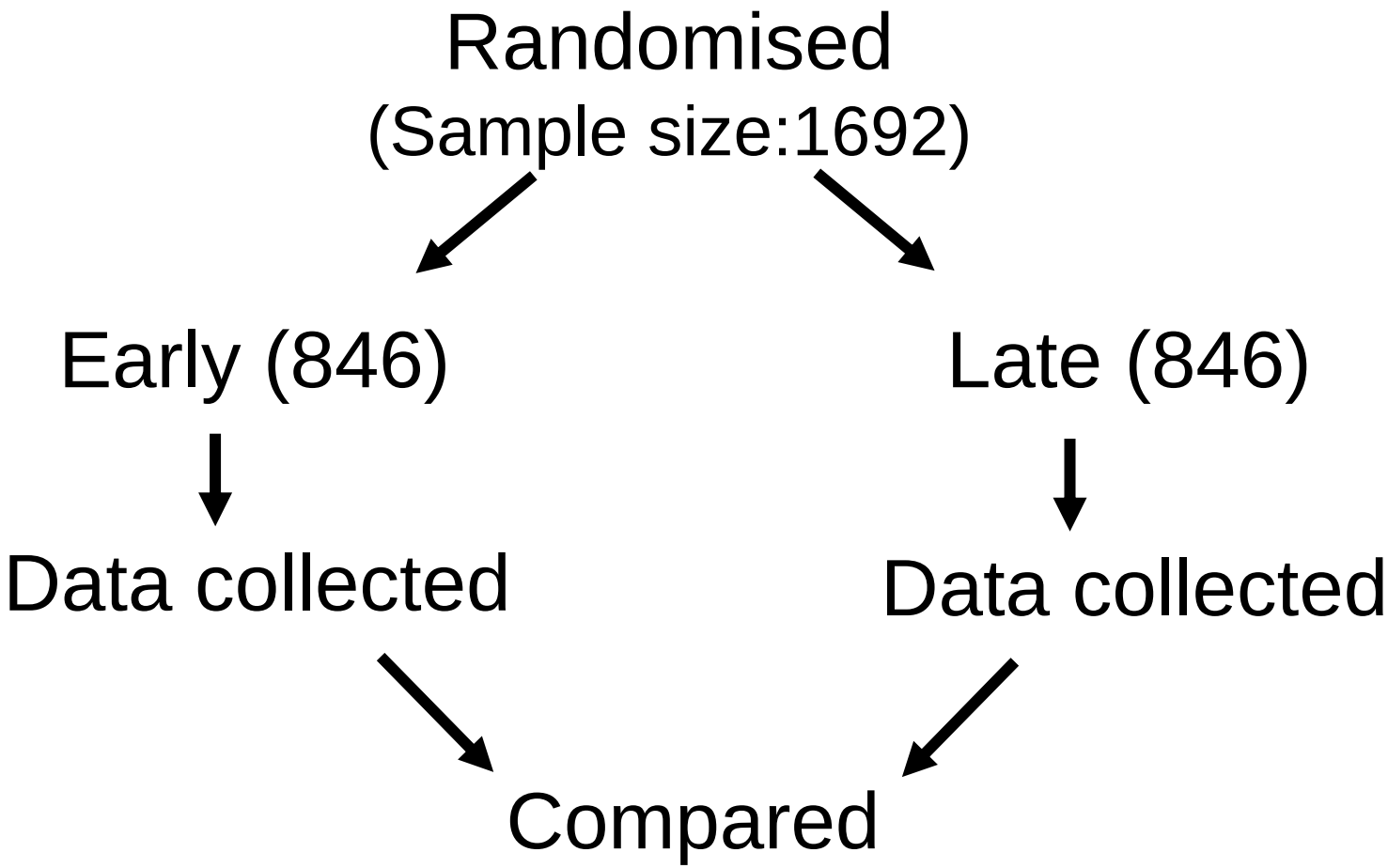
Brief details of patients who are eligible for the trial but who are not randomised will be recorded on the Patient Screening Log.

Recording this information is to establish an unbiased case selection and full reporting according to the CONSORT statement.

Patients suitable for the trial



Randomised Patients



Recruitment Period

Main Phase Recruitment began Jan 2005 and is likely to continue to end April 2008

Status of patient recruitment to date:

340 Patients recruited

(as of 31 May 06)

Target 1,692

Data Collection

Trial Forms

All trial documentation and data collection forms are provided by the co-ordinating trial office.

Forms are standardised across the trial, with each ICU having a unique centre code number by which they are identified.

For ICUs involved in PAC-Man, data collection is similar.

Trial Forms
Case Report Forms (CRFs)

1. **Patient Data Booklet (PDB)**

   Covers patient's stay in ICU

2. **Hospital Discharge Form**

   Covers patient's stay ICU discharge to Hospital Discharge

   3 questions only: patient status and date of discharge/death, whether tracheostomy still in place at hospital discharge.

FAQs

Q: Does it matter whether we do a surgical or percutaneous tracheostomy on an individual patient?

A: No, use whatever is clinically indicated. We collect this information on the procedure-related data collection form.

Q: Does it matter which percutaneous technique we use on an individual patient?

A: No, use whatever is clinically indicated. We collect this information on the procedure-related data collection form.

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. We collect this information on the procedure-related data collection form.

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: 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: If on day ten (late group allocation), 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).

Status of ICU recruitment:

List of ICUs Collaborating/ Finalising approvals

Aberdeen Royal Infirmary

Alexandra Hospital, Redditch

Barnet Hospital, London

Barnsley District Hospital

Bedford Hospital

Castle Hill Hospital, E Yorkshire

Causeway Hospital, Co Londonderry

Chorley Hospital, Lancashire

City General Hospital, Stoke on Trent

City Hospital, Birmingham

Countess of Chester Hospital

Derriford Hospital, Plymouth

Dumfries and Galloway Hospital

Eastbourne District General Hospital

Freeman Hospital, Newcastle

Glan Clwyd District General Hospital

Glenfield Hospital, Leicester

Hairmyres Hospital, Scotland

Huddersfield Royal Infirmary

Hull Royal Infirmary

James Cook University Hospital, Middlesbrough

James Paget Hospital, Norfolk

John Radcliffe Hospital, Oxford

King's College Hospital (Liver ICU), London

King George Hospital, Essex

Kingston Hospital, Surrey

Leeds General Infirmary

Leicester Royal Infirmary

Luton & Dunstable Hospital

Manchester Royal Infirmary (Cardiac Surgery ICU)

Manchester Royal Infirmary (General ICU)

Medway Maritime Hospital, Kent

New Cross Hospital, Wolverhampton

Ninewells Hospital and Medical School, Dundee

North Middlesex Hospital, London

Peterborough District Hospital

Pilgrim Hospital, Lincolnshire

Princess Alexandra Hospital, Essex

Queen Alexandra Hospital, Portsmouth

Queen's Hospital - Burton-on-Trent

Rochdale Infirmary

Royal Alexandra Hospital, Paisley

Royal Bournemouth Hospital

Royal Cornwall Hospital, Truro

Royal Devon & Exeter Hospital, Exeter

Royal Hampshire Hospital, Winchester

Royal Infirmary of Edinburgh

Royal Lancaster Infirmary

Royal Surrey County Hospital, Guildford

St Richards Hospital, Chichester

St Thomas' Hospital, London

Southampton General Hospital

South Tyneside Hospital

Sunderland Royal Hospital

Taunton & Somerset Hospital, Taunton

Torbay Hospital, Torquay

University College Hospital, London

University Hospital Lewisham, London

Weston General Hospital

Whiston Hospital, Liverpool

Whittington Hospital, London

Worthing Hospital

Wythenshawe Hospital, Manchester

Yeovil District General Hospital

York District Hospital

Would you like to collaborate?

The steps involved in joining TracMan are:

1. All ICU consultants should discuss the Protocol/view this presentation. All need to agree to abide by the Protocol.

2. A **Principal Investigator** (PI) will need to be identified, this person will act as the lead for the TracMan trial in your ICU

3. The PI should contact the trial office (Email: TracMan@nda.ox.ac.uk, tel: 01865 857627) expressing an interest.

- Once the Trial Office receives basic details about the PI and their unit, we will draft the necessary local approvals.
- Main Research Ethics Committee (MREC) Approval has already been obtained.
- All contact about the trial will be through the PI who will disseminate trial information locally.
- Once local approvals are finalised, the trial documentation will be couriered to your ICU.
- TracMan is an ‘academic’ trial funded by the Intensive Care Society/Medical Research Council. There is no funding for individual ICUs, we rely on your goodwill to address the research question.

We hope you have found this presentation informative and look forward to hearing from you

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