



Tracheostomy Management in Critical Care

HOW TO RANDOMISE A PATIENT

Q: I think I've got a suitable patient, what do I do?

A:

1. Go to the TracMan Trial Recruitment Box on your ICU
2. Pick up a Recruitment Pack envelope and read the outside cover
3. Work through the five questions

Five questions on Recruitment Pack envelope

1. Is the patient currently intubated with an endotracheal tube?
2. Is there a high chance the patient will require 7 days or more of ventilatory support during their ICU stay?
3. Has the patient been on the ICU less than 4 days?
4. Is the recruiting consultant 'uncertain' about whether an 'early' or 'late' tracheostomy is more appropriate for this patient?
5. Confirm you would be able to carry out a tracheostomy within 4 days of the patients ICU admission date/time (if patient randomised to early group).

*If **no** to **any** question, patient **cannot** be in trial (check again tomorrow)*

*If **yes** to **all** questions, **open envelope***





Patient Data Booklet

Centre code:

Patient's initials:

Patient's trial number:

Patient's postcode:

ICNARC Case Mix Programme
Admission Number:
(if applicable)

Patient Data
Booklet
(PDB) is
inside the
Envelope

White top copy
Yellow copy

Card flap to go
between
pages to stop
leaking to
next page



- Read instructions on inside page of PDB
- Instructions always on left hand pages, forms to be completed on right hand pages
- Work through the booklet page by page
- Complete page 1 'Assessment Sheet'

Assessment Sheet

The assessment sheet asks you to write the **date and time of the patient's ICU admission.**

You are then asked to calculate a 4 day (96hrs) deadline from date/time of admission.

Patient Data Booklet

- Tick questions on page 3, Inclusion/Exclusion Check Sheet' to check patient not excluded from trial according to general exclusion criteria

Inclusion Check

1. Confirm this patient has type 1 or type 2 respiratory failure
2. Confirm that there is a high chance that this patient will require a further 7 days or more of ventilatory support during their ICU stay
3. Confirm that you are uncertain about whether an “early” or “late” tracheostomy is more appropriate for this patient
4. Confirm you have the facilities to carry out the tracheostomy within the 1 to 4 day deadline stated on page 1 (if randomised to early tracheostomy)

If you tick ‘**no**’ to any of these the patient is **excluded** and cannot be in the trial

If you tick ‘**yes**’ to the above, **proceed** with the Exclusion Criteria Check



Exclusion Check

1. Is an immediate tracheostomy required?
2. Did the patient have a tracheal stoma or tracheostomy tube in situ on admission to the ICU?
3. Does the patient have chronic hypercarbic (type 2) respiratory failure due to a chronic neurological disease?
4. Was the patient transferred to your ICU from another ICU?
5. Has the patient previously been enrolled in the TracMan trial?
6. Is the patient/relative unable to speak English or not able to understand written or oral information (and no translator available)?
7. Was the patient 'legally incompetent' prior to hospital admission (i.e. Sectioned under the Mental Health Act)?

If tick '**yes**' to any of the above, the patient is **excluded** and **cannot** be in the trial.

If '**no**' to **all** of the above, **proceed** with obtaining consent/no objection from patient/relative

Obtaining Consent/No Objection

1. Patients who **have** capacity to consent prior to randomisation: go to *black box* 'Patient consent forms' in recruitment box and take out Patient Information Sheet and Consent Form.
2. Patients who **do not** have capacity to consent prior to randomisation: go to *blue box* 'Relative 'no objection' forms' in recruitment box and take out Relative covering statement/Information Sheet/'No objection' Form.

If patient/relative **refuses**, patient is **excluded** and **cannot** be randomised to the trial.

Patient/Relative Agrees

- Complete Trial Entry Sheet on page 5 (questions 15-25)

Trial Entry Sheet (Part 1)

TRIAL ENTRY SHEET

Once you have obtained consent/'No objection' please complete the information requested below

PATIENT'S ADMISSION DATE/TIME

Please transcribe the ICU admission date and time from the Assessment Sheet on page 1 into the boxes below:

15 Admission date: / / **16** Admission time: : 24 hr clock

PATIENT'S IDENTIFIERS

17 Surname:
18 Firstname:
19 Postcode:
20 Date of birth: / / **21** Sex (tick one): Male Female

PATIENT'S MAJOR CLINICAL SYNDROME

22 Which option below best describes the patient's major clinical syndrome? (tick one box only)

- | | |
|--|---|
| <input type="checkbox"/> Intracranial pathology | <input type="checkbox"/> Pulmonary pathology |
| <input type="checkbox"/> Altered consciousness level due to drug or metabolic causes | <input type="checkbox"/> Burns |
| <input type="checkbox"/> Peripheral nervous system or muscular disorder or weakness | <input type="checkbox"/> Decompensated (congestive) heart failure |
| | <input type="checkbox"/> None of the above (state): _____ |

23 Was **signed** consent/'No objection' obtained prior to randomisation?
(tick appropriate box) Yes No If only **verbal** 'No objection' obtained, you may randomise patient but signed 'No objection' should be obtained as soon as possible.

24 Name of consultant entering patient into the trial (PRINT):

25 Name of person making telephone call to randomisation service (PRINT):

Patient/Relative Agrees

- You are now ready to telephone the randomisation service
- Telephone number provided on page 5.

The Randomisation Service

- Experienced trials service unit
- Separate from Trial Office
- Human operator
- Cannot answer general trial questions (only to be used for randomisation)
- Open 24hrs a day/7days a week

During the call

- You will be asked questions 15-25 on page 5 in the order they appear on the form
- The operator will then give you the allocation and the unique trial number for this patient

Trial Entry Sheet (Part 2)

RANDOMISING THE PATIENT

Please telephone the **Randomisation Service on 01865 240972**. You will be asked for the information on page 3 first, followed by the information on this sheet. The questions will be asked in the order as they appear on the sheets. Please tick the box below that applies to the **random allocation** given to you over the telephone for this patient. You will also be given the **time** and **date** that applies to the tracheostomy placement. Write the time and date given in the appropriate box.

'Early' Tracheostomy: Tracheostomy to be performed on day 1-4 post admission to ICU <input type="checkbox"/> ↓	RANDOM ALLOCATION	'Late' Tracheostomy: No tracheostomy before day 10 post admission to ICU <input type="checkbox"/> ↓
Tracheostomy to be performed before: Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 24 hr clock Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 0 y		Tracheostomy to be performed on or after: Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> 24 hr clock Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 0 y

The operator will then give you a trial number for this patient.

PATIENT'S TRIAL NUMBER IS:

The operator will also give you a date which reflects the 30 day post-randomisation date for this patient.

PATIENT'S 30 DAY DATE IS:

 / / 2 0 0 y

Immediately after randomisation

- Write the patients unique **trial number** and **initials** on **each page** of the Patient Data Booklet
- Place a sticker (attached to page 4) in the patients notes

The patient is now
in the trial!

See presentation
'So what data is being collected'
for information about 'Excluded Patients'

Thank you.

Any questions to your
Principal Investigator

or email:

lesley.morgan@nda.ox.ac.uk

Tel: 01865 857627