HOW TO RANDOMISE: Quick Guide

Only staff members who have received trial training (recorded on the Training Log) are able to randomise patients into the trial. These staff do not require GCP training.

If you do not meet these requirements, please contact your local research team.

1. **ASSESS patient eligibility using the paper Randomisation Form.**
   Record information on this form prior to accessing randomisation system.

2. **CONFIRM eligibility.** In particular, check exclusion criteria with the treating clinician i.e., the treating clinician considers that one trial intervention arm is either indicated or contraindicated.

3. **PRINT AND SIGN your name on the Randomisation Form**.
   Ensure the name of the staff who confirmed eligibility is completed if that is not you.

4. **RANDOMISE**
   Only patients admitted to the critical care unit that meet all of the inclusion criteria and none of the exclusion criteria **at the point of randomisation** are eligible for randomisation into the trial. Once a patient is confirmed eligible, randomisation should occur **as soon as possible** and will be prior to the start of any trial treatment.

RANDOMISE either via TELEPHONE or ONLINE: See instructions on the next page

Once randomised…

5. **RECORD all details on the Randomisation Form and in the patient's medical notes.**
   Ensure you have printed and signed your name on the Randomisation Form.

6. **FILE the Randomisation Form** in the patient's medical notes / give to research staff…[*adapt locally to your own process. Ultimately a copy of the form must be filed in the medical notes*]

POSSIBLE RANDOMISATIONS

Conservative oxygen therapy (intervention group): The lowest concentration of oxygen possible should be administered to maintain the patient's SpO_2 at 90(±2)%

- Please keep a copy of the intervention algorithm at the bedside.

Usual oxygen therapy:

- Defined by local practice, determined by treating clinician. Chosen SpO_2 targets should be documented daily.

7. **COMMUNICATE the treatment allocation to bedside staff.**
   Document target SpO_2 as appropriate.

8. **ENSURE appropriate treatment.**

<Leave documents at bedside e.g. intervention guide/sticker, treatment allocation bedside notice, labels in patient's notes…adapt for your site. Some posters/signs, labels are in section 6 of the ISF.>

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TELEPHONE SYSTEM:

- **Dial: 020 3384 6368**
- **Enter study number: 7102**
- **Enter your investigator number: XXX** *(assigned per site)*
- Enter details as on the pre-completed paper Randomisation Form. For each question you will be prompted to enter a value i.e., "1 for YES" "2 for NO" etc.
- You will then be given:
  - Treatment allocation to which the patient has been randomised (i.e. Conservative oxygen therapy or Usual oxygen therapy)
  - Date/time of randomisation
  - Patient trial number

Document these on the paper randomisation form exactly as they are given via the phone system. *An email with these details will also be sent to all your site team on the email notification list.*

ONLINE SYSTEM:

Access the randomisation website: https://www.sealedenvelope.com/access

Randomisation system (Sealed Envelope) generic login details if applicable:

- **Email address:** [XXXXX]
- **Password:** [XXXXX]
- Enter details as on the pre-completed paper Randomisation Form.
- You will then be given:
  - Treatment allocation to which the patient has been randomised (i.e. Conservative oxygen therapy or Usual oxygen therapy)
  - Date/time of randomisation
  - Patient trial number

Document these on the paper randomisation form exactly as they are given via the online system. *An email with these details will also be sent to all of your site team on the email notification list.*