

RECAST-3 - Working Practice Document

Title: Manual Randomisation, No. 007

There are 2 scenarios in which online randomisation cannot be performed as normal by a RECAST-3 site investigator:

1. Randomisation performed by the coordinating centre

The site investigator is unable to reach the RECAST-3 database from their location, but the RECAST-3 database itself is working.

2. Manual randomisation

The RECAST-3 database is unavailable, which means that no one (including the team at the co-ordinating centre) can perform any online data entry at all. Manual randomisation means that a person chooses whether the active RIC or sham device is used, without the use of computerised randomisation.

Randomisation performed by the coordinating centre

The following steps should be taken:

- As soon as the site discovers that they are unable to use the RECAST-3 database to randomise their eligible patient, they should contact the coordinating centre (0115 823 1770). If randomisation is taking place over a weekend or out-of-hours, please call one of the emergency randomisation numbers which are available when logging onto the trial database. **Ensure this number is written down in advance, and accessible to all staff in case of emergencies.**
- They should provide the member of the coordinating centre with the randomisation details and confirm that the patient is eligible, so that the coordinating centre is able to enter the details into the database and perform the randomisation on behalf of the site.
- The coordinating centre will inform the site of the treatment group that the patient has been assigned to (either RIC or sham device).
- Once data entry has been completed, a randomisation email will be sent to the centre as usual.
- The site can then proceed with the trial protocol and give the assigned treatment intervention to the trial participant. Once the RECAST-3 database is working at the site, the site should ensure the details on the randomisation form are correct and proceed with data entry as normal.

Manual randomisation

The following steps should be taken:

- As soon as the site discovers that they are unable to use the RECAST-3 database to randomise their eligible patient, the site should contact the coordinating centre (0115 823 1770). If randomisation is taking place over a weekend or out-of-hours, please call one of the emergency randomisation numbers which are available when logging onto the trial database. **Ensure this number is written down in advance, and accessible to all staff in case of emergencies.**

- If the coordinating centre also cannot access the RECAST-3 website, the manual randomisation process will take place.
- The site should provide the member of the coordinating centre with the randomisation details to confirm that the patient is eligible, according to the inclusion/exclusion criteria in the trial protocol.
- A member of the team at the coordinating centre will make a note of the randomisation details, to be entered onto the site as soon as any issues relating to the RECAST-3 database have been resolved.
- The coordinating centre will then randomly pick a treatment group and inform the site.
- The site can then proceed with the trial protocol and give the assigned treatment intervention to the trial participant.

Completing the randomisation CRF

The following steps should be taken by the **coordinating centre** at the earliest opportunity following manual randomisation to ensure that the reserved trial number will not be inadvertently used by the next randomisation performed (at the centre and for the trial as a whole):

- To enter a manual randomisation, first select the centre on the participant list and then select the link to "Randomise a new participant".
- In the "Enter manual randomisation" box, indicate that the treatment group has already been assigned manually and select the group from the drop-down list.
- Enter a full explanation and confirm that the correct centre has been selected.
- The randomisation data provided by the site at the time of the manual randomisation can then be entered as usual. The randomisation date/time must be entered manually.
- Once data entry has been completed, a randomisation email will be sent to the centre as usual.
- Once the RECAST-3 database is working at the site, the site should ensure the details on the randomisation form are correct and proceed with data entry as normal.