MACE-ICH Working Practice Document

Title: Manual Randomisation No. 003

In the event of technical problems, which cause computerised randomisation failure, sites should seek to randomise a patient over the telephone.

There are two scenarios in which online randomisation cannot be performed as normal by a MACE-ICH site investigator:

1. **Randomisation performed by the coordinating centre**
   The site investigator is unable to reach the MACE-ICH database from their location, but the MACE-ICH database itself is working.
2. **Manual randomisation**
   The MACE-ICH database is unavailable, which means that no one (including the team at the coordinating centre) can perform any online data entry at all.

Randomisation performed by the coordinating centre

The following steps should be taken:

1. As soon as the site discovers that they are unable to use the MACE-ICH 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 these numbers are written down in advance, and accessible to all staff in case of emergencies – in the event of the database being inaccessible, you will not be able to retrieve them.** These numbers may alter from time to time with staff changes and efforts should be made to keep an up-to-date list.
2. Sites will be required to provide all information requested on the randomisation CRF. When providing details over the telephone you will be required to confirm that the patient fulfils all the inclusion and none of the exclusion criteria.
3. A paper copy of the randomisation CRF will need to be completed and scanned to the MACE-ICH inbox MACE-ICH@nottingham.ac.uk.
4. The coordinating centre will enter the data into the system on behalf of the site. Advice regarding the arm to which the participant has been randomised will be given to the site investigator over the phone.
5. A randomisation email will be sent to the centre as usual.
6. The site can then proceed with the trial protocol. Once the MACE-ICH 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:

1. As soon as the site discovers that they are unable to use the MACE-ICH 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 these numbers are written down in advance, and accessible to all staff in case of emergencies – in the event of the database being inaccessible, you will not be able to retrieve them.** These numbers may alter from time to time with staff changes and efforts should be made to keep an up-to-date list.

2. If the coordinating centre also cannot access the MACE-ICH website, the manual randomisation process will take place.
3. Sites will be required to provide all information requested on the randomisation CRF. When providing details over the telephone you will be required to confirm that the patient fulfils all the inclusion and none of the exclusion criteria.
4. A paper copy of the randomisation CRF will need to be completed and scanned to the MACE-ICH inbox MACE-ICH@nottingham.ac.uk.
5. 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 MACE-ICH database have been resolved.
6. One of the medics listed as emergency randomisation contacts will use the following link to generate a true random number that will be 0 (standard care), 1 (one dose) or 2 (two doses): https://stroke.nottingham.ac.uk/?MI3 NB:- this page should be bookmarked (not the shortcut above which may not be available when the MACE-ICH site is down), preferably on both computer and mobile. For manual randomisation, you **must** take the first result given to avoid bias.
7. Advice regarding the arm to which the participant has been randomised will be given to the site investigator over the phone.
8. The site can then proceed with the trial protocol. Once the MACE-ICH 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.

Please take particular care to ensure that the patient fulfils all the inclusion and none of the exclusion criteria. The built-in checks with the computerised system are not available with telephone randomisation.

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 which treatment group was used
- 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. The manual randomisation details will be displayed. However, 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 MACE-ICH 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.