

Sealed
Envelope



Enter details

Randomise

Randomisation using Sealed Envelope

Standard operating procedure

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COMET

Cooling in Mild Encephalopathy Trial

IRAS ID: 326176 | REC: 23/LO/0853

1. Purpose

To outline the standardized process for participant randomisation using Sealed Envelope in the COMET trial, ensuring protocol compliance and the secure use iPad and QR code access.

2. Scope

This SOP applies to all personnel involved in the randomisation of participants in the COMET trial at participating sites.

3. Procedure

3.1 Pre-Randomisation Requirements

1. Eligibility Confirmation: Verify participant eligibility as per protocol criteria
2. Ensure signed informed consent is obtained prior to randomisation.
3. System Access: Confirm access to Sealed Envelope with unique credentials.
4. Ensure the study iPad is charged, connected to secure Wi-Fi, and the Sealed Envelope QR code is available for scanning.
5. Conduct a pre-randomisation system test to confirm functionality.

3.2 Randomisation Process

1. Accessing Sealed Envelope via QR Code on iPad and Log in using unique site credentials.
2. Input all required participant details into the system.
3. Review the entered data for accuracy and click the Randomise button.
4. Record the randomisation result displayed by the system.

3.3 Post-Randomisation Activities

1. Communicate the allocation result to relevant site staff.
2. Begin intervention promptly, ensuring compliance with the trial protocol (e.g., within the 6-hour time window from birth).
3. Document the randomisation outcome in the case report form (CRF) and clinical notes.
4. For participants allocated to the intervention arm (whole-body hypothermia) at non-cooling centres, arrange immediate transfer to a facility equipped for cooling therapy.

3.4 Summary Flow Diagram

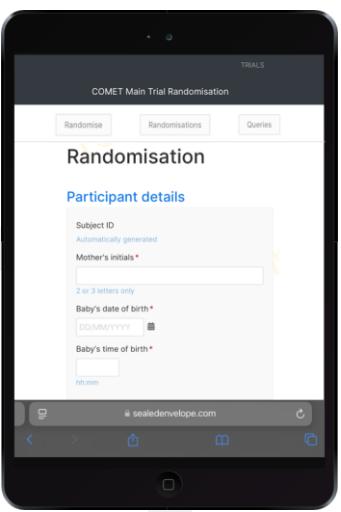
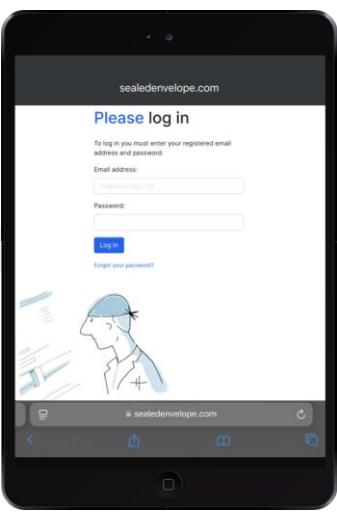
On the next page, a flow diagram summarizes the Randomisation steps.

Sealed Envelope

Open iPad Camera



Scan QR code

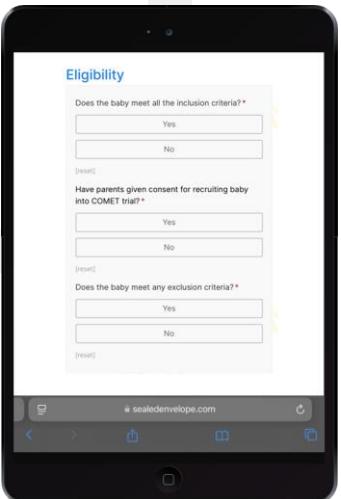


The first iPad screen shows the 'Please log in' page with fields for 'Email address' and 'Password', and links for 'Log in', 'Forgot your password?', and 'Create account?'. The second iPad screen shows the 'Randomisation' page under 'COMET Main Trial Randomisation', with fields for 'Subject ID' (Automatically generated), 'Mother's initials', 'Baby's date of birth' (DDMMYYYY), and 'Baby's time of birth'.

1 Log in

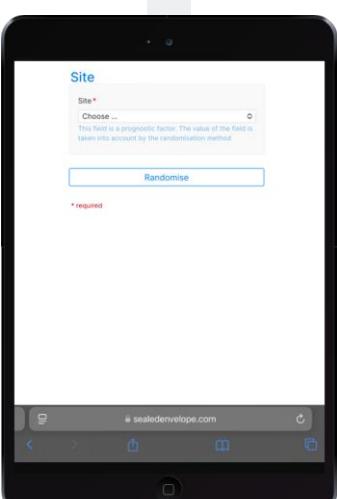


The iPad screen displays the 'NICHHD neurological examination' form, which is a grid of symptoms and their severity across various neurological categories. Categories include: 1. Level of consciousness, 2. Consciousability, 3. Posture, 4. Tone, 5. Reflex, and 6. Autonomic Nervous System. Each category has a 'NORMAL' row and 'MILD', 'MODERATE', and 'SEVERE' rows for each symptom.

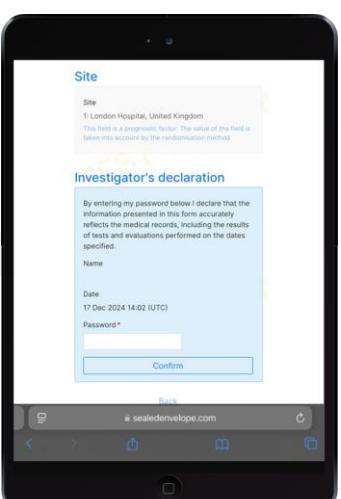


The iPad screen shows the 'Eligibility' form with three questions: 'Does the baby meet all the inclusion criteria?', 'Have parents given consent for recruiting baby into COMET trial?', and 'Does the baby meet any exclusion criteria?'. Each question has 'Yes' and 'No' radio button options.

2 Participant details



The iPad screen shows the 'Site' form with a 'Site *' field labeled 'Choose ...' and a note: 'This field is a prognostic factor. The value of the field is taken into account by the randomisation method.' A 'Randomise' button is at the bottom.



The iPad screen shows the 'Investigator's declaration' form with fields for 'Name', 'Date' (17 Dec 2024 14:02 (UTC)), and 'Password*'. A 'Confirm' button is at the bottom.

3 Eligibility

4 Sarnat staging

5 Site & Randomise

6 Confirm

4. Troubleshooting

1. If technical issues occur, including password-related issues, contact the central COMET study team (comet@imperial.ac.uk). Include the following details in the email:

- Your name.
- Your site name .
- The issue experienced (e.g., no reset email received).

2. In the event of unavailability of the Sealed Envelope system:

- Contact the central COMET study team to obtain randomisation by telephone.