

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

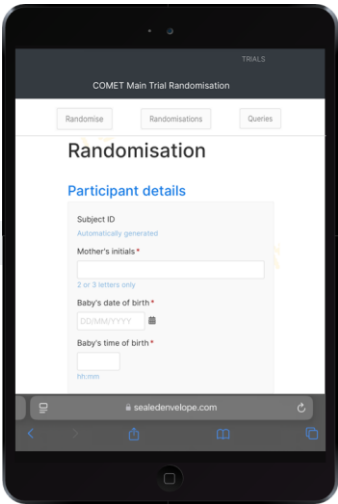
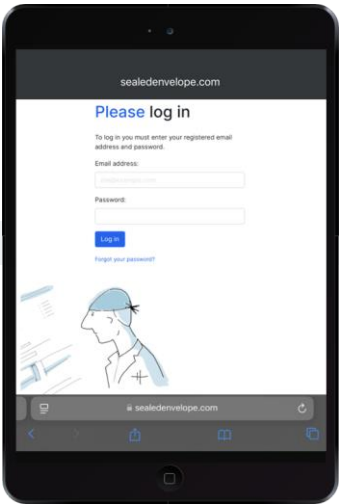
On the next page, a flow diagram summarizes the Randomisation steps.

Sealed Envelope

Open iPad Camera



Scan QR code



1 Log in

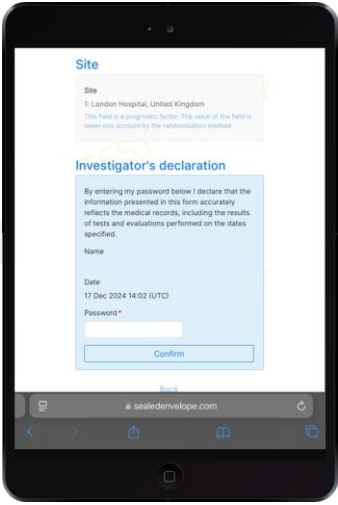
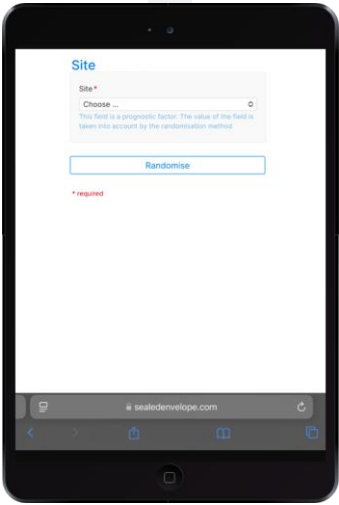
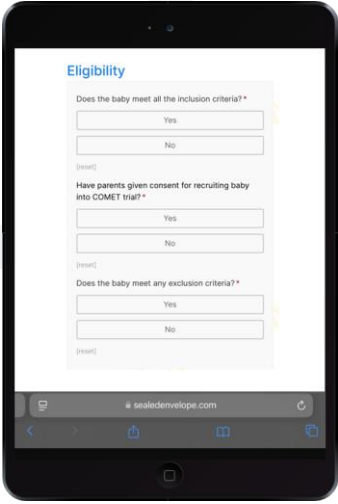
2 Participant details

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.