



Sugar or Salt trial:
Hyperosmolar therapy in
traumatic brain injury

Participant recruitment flowchart

01. Assess Patient Eligibility

Use the below Eligibility Criteria to assess patient eligibility:



Inclusion criteria:

- ✓ Adult ≥ 16
- ✓ Admission to ICU with TBI
- ✓ ICP $> 20\text{mmHg}$ for more than 5 mins despite stage 1 measures
- ✓ < 10 days from initial TBI
- ✓ Abnormal CT scan consistent with TBI

Exclusion criteria:

- ✗ Devastating brain injury with withdrawal of treatment anticipated in the next 24 hours
- ✗ Pregnancy
- ✗ Severe hyponatraemia (serum Na $> 155\text{mmol/L}$)
- ✗ 2 or more prior doses of hyperosmolar therapy given on ICU

02. Document Consent

Consent may be obtained pre- or post-enrolment (deferred):



Pre-enrolment consent:

- If there is sufficient time, obtain written informed consent from a personal or professional legal representative

Post-enrolment (Deferred) consent:

- If urgent treatment is needed and there is not sufficient time to obtain consent from a legal representative, enrol patient under deferred consent
- As soon as possible after the emergency, obtain written informed consent from personal or professional legal representative

03. Randomise the Patient

Once eligibility is confirmed, randomise the patient:



Randomise via trial database:

Link: <https://ctu.warwick.ac.uk/SOS>



- If you are delegated to randomise and have a database user login, you can randomise the patient through the trial database
- You will need to access from a site computer or whilst connected to VPN

Randomise via IVR phone line:

Tel: 024 7610 0792

- If you are delegated to randomise you can use the automated IVR phone line to randomise a patient regardless of if you have a database user login or not
- Your site has been emailed your unique site pin code
- Computer access is not required to use IVR

- If you are unable to access the database or use the IVR, there is also an [emergency randomisation phone line](#) you can call: 02476 150 402 (Mon-Fri 9-5 only)

04. Prescribe and Administer IMP



Once randomised, prescribe and administer the allocated IMP:

- The database/IVR system will allocate either Mannitol or Hypertonic Saline
- Prescribe and administer the allocated IMP using the SOS protocol dosing table and the patient's weight
- Each dose given must be as per the SOS dosing table