

TNO:

Site:



Screening and Eligibility Form

THIS CRF SHOULD BE COMPLETED FOR ALL PATIENTS ADMITTED TO ICU WITH TRAUMATIC BRAIN INJURY WHERE AN ICP BOLT HAS BEEN INSERTED

INCLUSION CRITERIA

Participants will be excluded if **ANY** of the following are No:

	YES	NO
1 Adult aged 16 years or above	<input type="checkbox"/>	<input type="checkbox"/>
2 Admission to ICU following traumatic brain injury	<input type="checkbox"/>	<input type="checkbox"/>
3 ICP > 20mmHg for more than 5 minutes despite stage 1 procedures	<input type="checkbox"/>	<input type="checkbox"/>
4 < 10 days from initial primary head injury	<input type="checkbox"/>	<input type="checkbox"/>
5 Abnormal CT scan consistent with TBI	<input type="checkbox"/>	<input type="checkbox"/>

EXCLUSION CRITERIA

Participants will be excluded if **ANY** of the following are Yes:

	YES	NO
1. Devastating brain injury with withdrawal of treatment anticipated in the next 24 hours	<input type="checkbox"/>	<input type="checkbox"/>
2. Pregnancy	<input type="checkbox"/>	<input type="checkbox"/>
3. Severe hyponatraemia (serum sodium > 155 mmol/L)	<input type="checkbox"/>	<input type="checkbox"/>
4. 2 or more prior doses of hyperosmolar therapy given on ICU	<input type="checkbox"/>	<input type="checkbox"/>

If yes, record the name of the medically qualified doctor or advanced clinical practitioner who has confirmed the patient is eligible to be enrolled in the SOS trial, and the date and time confirmed. This should also be reflected in the medical notes.

Has a medically qualified doctor or advanced clinical practitioner* assessed and confirmed that the patient is eligible?	Yes <input type="checkbox"/> No <input type="checkbox"/>
*If an advanced clinical practitioner has confirmed eligibility, please confirm that the diagnosis of TBI has been documented	Yes <input type="checkbox"/> No <input type="checkbox"/>
Name of doctor/advanced clinical practitioner	<input type="text"/>
Signature of doctor/advanced clinical practitioner	<input type="text"/>
Date and time confirmed	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> DD/MMM/YYYY HH:MM

If the patient is not enrolled, please give the reason for non-enrolment (tick the primary reason only):

	YES	NO
Patient enrolled in the SOS trial?	<input type="checkbox"/>	<input type="checkbox"/>
If IVR phone line used to enrol, name of person who completed randomisation	<input type="text"/>	

REASON FOR NON-ENROLMENT

Eligible but consent declined by personal legal representative	<input type="checkbox"/>
Eligible but consent declined by professional legal representative	<input type="checkbox"/>
Not eligible	<input type="checkbox"/>

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No one with delegated responsibility (on delegation log) available to enrol patient	<input type="checkbox"/>
Logistical e.g. no mannitol/hypertonic saline available	<input type="checkbox"/>
Trial on hold	<input type="checkbox"/>
Already enrolled in CTIMP, specify _____	<input type="checkbox"/>
Forgot/missed	<input type="checkbox"/>
Other, specify _____	<input type="checkbox"/>