



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

! **Eligibility must be confirmed by a doctor** prior to the patient being enrolled and **the Screening and Eligibility Form signed by that doctor** as soon as practicably possible after enrolment.

- Inclusion Criteria:**
- Adult aged ≥ 16 years old
 - Admission to ICU following TBI
 - ICP >20 mmHg for more than 5mins despite stage 1 procedures
 - <10 days from initial primary head injury
 - 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 mmol/L)
 - 2 or more prior doses of hyperosmolar therapy given on ICU

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

! **Eligibility must be confirmed by a doctor** prior to the patient being enrolled and **the Screening and Eligibility Form signed by that doctor** as soon as practicably possible after enrolment.

- Inclusion Criteria:**
- Adult aged ≥ 16 years old
 - Admission to ICU following TBI
 - ICP >20 mmHg for more than 5mins despite stage 1 procedures
 - <10 days from initial primary head injury
 - 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 mmol/L)
 - 2 or more prior doses of hyperosmolar therapy given on ICU

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

! **Eligibility must be confirmed by a doctor** prior to the patient being enrolled and **the Screening and Eligibility Form signed by that doctor** as soon as practicably possible after enrolment.

- Inclusion Criteria:**
- Adult aged ≥ 16 years old
 - Admission to ICU following TBI
 - ICP >20 mmHg for more than 5mins despite stage 1 procedures
 - <10 days from initial primary head injury
 - 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 mmol/L)
 - 2 or more prior doses of hyperosmolar therapy given on ICU

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

! **Eligibility must be confirmed by a doctor** prior to the patient being enrolled and **the Screening and Eligibility Form signed by that doctor** as soon as practicably possible after enrolment.

- Inclusion Criteria:**
- Adult aged ≥ 16 years old
 - Admission to ICU following TBI
 - ICP >20 mmHg for more than 5mins despite stage 1 procedures
 - <10 days from initial primary head injury
 - 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 mmol/L)
 - 2 or more prior doses of hyperosmolar therapy given on ICU

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

! **Eligibility must be confirmed by a doctor** prior to the patient being enrolled and **the Screening and Eligibility Form signed by that doctor** as soon as practicably possible after enrolment.

- Inclusion Criteria:**
- Adult aged ≥ 16 years old
 - Admission to ICU following TBI
 - ICP >20 mmHg for more than 5mins despite stage 1 procedures
 - <10 days from initial primary head injury
 - 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 mmol/L)
 - 2 or more prior doses of hyperosmolar therapy given on ICU

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

! **Eligibility must be confirmed by a doctor** prior to the patient being enrolled and **the Screening and Eligibility Form signed by that doctor** as soon as practicably possible after enrolment.

- Inclusion Criteria:**
- Adult aged ≥ 16 years old
 - Admission to ICU following TBI
 - ICP >20 mmHg for more than 5mins despite stage 1 procedures
 - <10 days from initial primary head injury
 - 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 mmol/L)
 - 2 or more prior doses of hyperosmolar therapy given on ICU

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

Checklist for enrolment:

- ✓ Have you completed trial training and signed the SOS training log?
- ✓ Complete and sign the paper Screening and Eligibility CRF.
- ✓ Ensure time eligibility was assessed is recorded on the database when randomising and on the paper CRF—these should match.
- ✓ Document the justification for the patient meeting **ALL** of the eligibility criteria; this includes recording the patient's **ICP and serum Na values** at the time of confirming eligibility in the medical notes.
- ✓ Record the patient's **weight/estimated weight** used to calculate the trial drug dose in the medical notes.
- ✓ Use the SOS **dosing table** to calculate the allocated trial drug dose to be administered.

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

Checklist for enrolment:

- ✓ Have you completed trial training and signed the SOS training log?
- ✓ Complete and sign the paper Screening and Eligibility CRF.
- ✓ Ensure time eligibility was assessed is recorded on the database when randomising and on the paper CRF—these should match.
- ✓ Document the justification for the patient meeting **ALL** of the eligibility criteria; this includes recording the patient's **ICP and serum Na values** at the time of confirming eligibility in the medical notes.
- ✓ Record the patient's **weight/estimated weight** used to calculate the trial drug dose in the medical notes.
- ✓ Use the SOS **dosing table** to calculate the allocated trial drug dose to be administered.

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

Checklist for enrolment:

- ✓ Have you completed trial training and signed the SOS training log?
- ✓ Complete and sign the paper Screening and Eligibility CRF.
- ✓ Ensure time eligibility was assessed is recorded on the database when randomising and on the paper CRF—these should match.
- ✓ Document the justification for the patient meeting **ALL** of the eligibility criteria; this includes recording the patient's **ICP and serum Na values** at the time of confirming eligibility in the medical notes.
- ✓ Record the patient's **weight/estimated weight** used to calculate the trial drug dose in the medical notes.
- ✓ Use the SOS **dosing table** to calculate the allocated trial drug dose to be administered.

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

Checklist for enrolment:

- ✓ Have you completed trial training and signed the SOS training log?
- ✓ Complete and sign the paper Screening and Eligibility CRF.
- ✓ Ensure time eligibility was assessed is recorded on the database when randomising and on the paper CRF—these should match.
- ✓ Document the justification for the patient meeting **ALL** of the eligibility criteria; this includes recording the patient's **ICP and serum Na values** at the time of confirming eligibility in the medical notes.
- ✓ Record the patient's **weight/estimated weight** used to calculate the trial drug dose in the medical notes.
- ✓ Use the SOS **dosing table** to calculate the allocated trial drug dose to be administered.

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

Checklist for enrolment:

- ✓ Have you completed trial training and signed the SOS training log?
- ✓ Complete and sign the paper Screening and Eligibility CRF.
- ✓ Ensure time eligibility was assessed is recorded on the database when randomising and on the paper CRF—these should match.
- ✓ Document the justification for the patient meeting **ALL** of the eligibility criteria; this includes recording the patient's **ICP and serum Na values** at the time of confirming eligibility in the medical notes.
- ✓ Record the patient's **weight/estimated weight** used to calculate the trial drug dose in the medical notes.
- ✓ Use the SOS **dosing table** to calculate the allocated trial drug dose to be administered.

EudraCT Number: 2019-001688-66



Sugar or Salt (SOS) Trial:

Hyperosmolar therapy in traumatic brain injury

Checklist for enrolment:

- ✓ Have you completed trial training and signed the SOS training log?
- ✓ Complete and sign the paper Screening and Eligibility CRF.
- ✓ Ensure time eligibility was assessed is recorded on the database when randomising and on the paper CRF—these should match.
- ✓ Document the justification for the patient meeting **ALL** of the eligibility criteria; this includes recording the patient's **ICP and serum Na values** at the time of confirming eligibility in the medical notes.
- ✓ Record the patient's **weight/estimated weight** used to calculate the trial drug dose in the medical notes.
- ✓ Use the SOS **dosing table** to calculate the allocated trial drug dose to be administered.

EudraCT Number: 2019-001688-66