



Sugar or Salt trial:
Hyperosmolar therapy in
traumatic brain injury

SOS GCP training requirements

A copy of all GCP targeting training material can be found in your site file and also on our webpage: [Training Resources \(warwick.ac.uk\)](https://www.warwick.ac.uk/training-resources)

Evidence of training **MUST** be documented on the trial Training log or [online confirmation of training form](#).

Trial Role/Responsibility	Who can do this role	Full GCP training required? (GCP certificate)	Minimum GCP training required
Screening	Any member of the team who has been trained can assess eligibility.	No	- SOS Targeted Training – Patient recruitment and trial interventions
Confirming eligibility	Must be either a medically-qualified doctor or an advanced clinical practitioner. Ideally this individual should sign the Screening and Eligibility CRF to confirm eligibility prior to the patient being enrolled. If this is not possible, the CRF should be signed as soon as possible after the patient has been enrolled.	No	- SOS Targeted Training – Patient recruitment and trial interventions
Performing randomisation	Any member of the team who has been trained.	No	- SOS Targeted Training – Patient recruitment and trial interventions
Prescribe mannitol/hypertonic saline	Anyone who would usually prescribe mannitol/hypertonic saline	No	- SOS Targeted Training – Patient recruitment and trial interventions
Administer IMP	Anyone who would usually administers mannitol/hypertonic saline	No	None
Informed consent	Doctor or research nurse (if permitted by Trust policy)	No	- SOS Targeted consent GCP training
Data collection	Anyone who has been trained on trial data collection	No	- SOS Targeted data collection GCP training
SAE causality assessment and sign off	PI or delegate. (Must be a medically-qualified doctor)	No	- SOS Targeted SAE GCP training