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A pilot study of the effect of a hypertonic saline /dextran solution compared to mannitol in the management of raised intracranial pressure

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/04/2018	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N0185139336

Study information

Scientific Title

A pilot study of the effect of a hypertonic saline/dextran solution compared to mannitol in the management of raised intracranial pressure

Study objectives
Whether hypertonic saline/dextran produces greater lowering of raised intracranial pressure and for a longer duration that an equiosmolar dose of mannitol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nervous System Diseases: Raised Intracranial Pressure (ICP)

Interventions
Patients on the intensive care unit with brain injury and an intracranial monitor fitted will be eligible for entry into the study. Those with persistently elevated ICP despite usual management will be randomised to receive either mannitol 0.25 g/kg (the standard treatment at this point) or an equiosmolar dose of HSD. ICP will be recorded each minute using the standard ICU monitors. Patients will be eligible to receive up to three doses of the drug (Mannitol or HSD) if their clinical condition warrants it and there are no contra-indications. ICP will be monitored, for the purposes of the study, until eight hours since the last dose of HSD/mannitol.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hypertonic Saline/Dextran (HSD) Solution, Mannitol

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date

31/12/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2001

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Plymouth Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes