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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2001

Completion date
31/12/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Plymouth Hospitals NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration