

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/04/2018	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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Contact details

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Derriford
Plymouth
United Kingdom
PL6 8DH

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 than 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