ISRCTN62699180 https://doi.org/10.1186/ISRCTN62699180

Efficiency of 7.2% hypertonic saline hydroxyethyl starch 200/0.5 versus mannitol 15% in the treatment of increased intracranial pressure in neurosurgical patients

Submission date
23/06/2005

Recruitment status
No longer recruiting

Registration date
24/06/2005

Overall study status
Completed

Last Edited
15/04/2008

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Severe brain injury can lead to a brain edema with increased intracranial pressure. This fact leads to a reduced cerebral blood flow and cerebral oxygenation. These situations can extend the brain edema with a possible poor patient outcome.

7.2% hypertonic saline hydroxyethyl starch 200/0.5 is more effective compared to mannitol 15% in the treatment of increased intracranial pressure in neurosurgical patients.

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

Health condition(s) or problem(s) studied
Increased intracranial pressure

Interventions
Cerebral perfusion pressure (CPP) directed therapy with CPP >70 mmHg, sedation, normoventilation.

If ICP >20 mmHg patients receive either 7.2% hydroxyethyl starch 200/0.5 or mannitol 15%.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
7.2% hypertonic saline hydroxyethyl starch 200/0.5, mannitol 15%

Primary outcome measure
ICP <15 mmHg

Secondary outcome measures
Survival, discharge status

Overall study start date
01/02/2003

Completion date
31/08/2004

Eligibility

Key inclusion criteria
1. Neurosurgical patients >18 years with severe neuronal damage being at risk of increased intracranial pressure (ICP)
2. Cerebral edema - visualized by computed tomography (CT) scan, continuous monitoring of ICP

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Exclusion criteria were elevated ICP due to space occupying lesions with indication for neurosurgical intervention, severe renal failure, metabolic disorders, initial serum sodium >150 mmol/l and initial serum osmolarity >320 mosm/kg

Date of first enrolment
01/02/2003

Date of final enrolment
31/08/2004

Locations

Countries of recruitment
Germany

Study participating centre
Martin-Luther-University Halle
Halle
Germany
06097

Sponsor information

Organisation
Martin-Luther-University Halle - Department of Anesthesia and Critical Care (Germany)

Sponsor details
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Sponsor type
University/education

Website
http://www.experimentelle-anaesthesie.de

ROR
https://ror.org/05gqaka33

Funder(s)

Funder type
University/education

Funder Name
Self-funded trial, Department of Anesthesia and Critical Care, Martin-Luther University Halle (Germany)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	05/10/2005		Yes	No