

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

<b>Submission date</b> 23/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/06/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/04/2008	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## 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

**Study type(s)**

Treatment

**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(s)**

ICP <15 mmHg

**Key secondary outcome(s)**

Survival, discharge status

**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

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### 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)

## 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

## 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?
<a href="#">Results article</a>	Results:	05/10/2005		Yes	No