Cerebrospinal fluid concentrations of polyols following traumatic brain injury

Published: 13-06-2024
Last updated: 07-03-2025

Primary objective:i. Investigate cerebrospinal fluid (CSF) polyol concentrations in patients following traumatic brain injurySecondary objectives:i. Investigate the association between plasma glucose, CSF glucose and CSF polyols following traumatic...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON56843

Source
ToetsingOnline

Brief title
SUGAR-TBI

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Injuries NEC
- Neurological disorders NEC

Synonym
neurotrauma, Traumatic brain injury

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W,Nederlanse Vereniging voor Anesthesiologie

Intervention

Keyword: Cerebral glucose metabolism, Neurometabolism, Polyol, TBI

Outcome measures

Primary outcome

i. CSF polyol (sorbitol and fructose) concentrations

Secondary outcome

i. CSF polyol : plasma glucose ratios.

ii. CSF polyol : CSF glucose ratios.

iii. Plasma and CSF neuroinflammatory markers: S100-beta, neuron specific

enolase, neurofilament light, IL-6, TNF-alpha, Il-10, interferon-gamma.

Study description

Background summary

Traumatic brain injury is the leading cause of death and disability in children and adults aged 1 to 44 years. The direct consequences of a single traumatic brain injury (TBI) or repetitive insults can result in various secondary pathological conditions.
Under normal circumstances, the brain uses glucose as an obligate energy source. However, during glucose excess, neurotoxic polyols are generated. The brain uses glucose as an obligate energy source and generates polyols during glucose excess. Following TBI, the brain utilizes less glucose due to sedative medications, the injury itself and because of a hyperglycaemic stress response. As such we hypothesise that the brain produces increased amounts of neurotoxic polyols after TBI.
We propose to conduct a prospective observational cohort study to describe the polyol concentrations in the cerebrospinal fluid (CSF) in participants admitted to the intensive care unit following TBI, who have required insertion of an External Ventricular Drain (EVD) as part of their clinical management, and determine associations between CSF polyol concentration, plasma glucose and markers of neuroinflammation.

Study objective

Primary objective:
i. Investigate cerebrospinal fluid (CSF) polyol concentrations in patients following traumatic brain injury

Secondary objectives:
i. Investigate the association between plasma glucose, CSF glucose and CSF polyols following traumatic brain injury.
ii. Investigate the relationship between CSF polyol concentration and plasma and CSF markers of neuroinflammation (S100-beta, neuron specific enolase, neurofilament light, IL-6, TNF-alpha, Il-10, interferon-gamma) in patients with TBI.

Study design

Prospective monocenter cohort study with an expected duration of 2 years. This study will be conducted at the Amsterdam UMC, location AMC.

Study burden and risks

This study has no additional risks beyond standard care, as there are no additional blood or liquor collection moments for research purposes. Patients will undergo three times a week blood and liquor tests for this study. The blood collection will involve 1 tube of blood of 4 ml at a time, with a maximum collection of 40 ml of blood per patient. This blood collection will take place at the same time as the department's blood collection. The liquor examination takes place in the liquor drained from the Extra Ventricular Drain (EVD). There will be no additional liquor collection. Therefore, the burden on the subject is minimal and the risks are similar to those of standard care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Adult (aged at least 18 years)
• Clinical diagnosis of moderate to severe TBI, classified by Glasgow Coma Scale (GCS), with GCS <9 indicating severe TBI and GCS 9-12 moderate TBI
• Extra ventricular drain in situ

Exclusion criteria

• Admission to the ICU is solely for the purposes of palliative care or confirmation of organ donation
• Advanced care directive or previously stated wish not to be included in research activities
• Past medical history of diabetes mellitus
• HbA1c >= 6.5%

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-12-2024
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	13-06-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2025
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85513.018.23
Other	TBA