Cerebrospinal fluid metabolites as marker for the severity of progressive post-hemorrhagic ventricular dilatation in preterm infants

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1. Is the concentration of brain specific proteins in CSF higher in newborn who are treated after high threshold as compared to newborns who are treated after low threshold?2. Is there any relationship between the concentration of brain specific...

Ethical review	Approved WMO
Status	Pending
Health condition type	Increased intracranial pressure and hydrocephalus
Study type	Observational non invasive

Summary

ID

NL-OMON30135

Source
ToetsingOnline

Brief title
Cerebrospinal fluid metabolites in post-hemorrhagic ventricular dilatation

Condition

- Increased intracranial pressure and hydrocephalus
- Neonatal and perinatal conditions

Synonym
hydrocephalus after cerebral bleeding

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,aanvraag voor subsidie bij de Hersenstichting is ingediend

Intervention

Keyword: brain specific protein, post-hemorrhagic, ventricular dilatation

Outcome measures

Primary outcome

The concentration of brain specific proteins and glucose in CSF, the severity

of ventricular dilatation, VP drain insertion and neurodevelopmental outcome at

the age of 2 year.

Secondary outcome

None.

Study description

Background summary

Post-hemorrhagic ventricular dilatation (PHVD) as complication of intraventricular hemorrhage in preterm infants may result in impaired cerebral perfusion, resulting in ischemic brain lesion and impaired neurodevelopmental outcome. As treatment reduction of ventricular dilatation can be achieved by intermittent removal of cerebrospinal fluid (CSF) through a puncture of subcutaneous ventricular catheter reservoir (SVCR). Increased brain specific proteins in CSF are related to brain tissue damage. It can be expected that there is a relationship between the concentration of brain specific proteins and glucose in CSF on the one side and the severity of PHVD and neurodevelopmental outcome on the other side. This relationship has not been investigated yet. When there is a strong relationship, the concentration of these CSF metabolites can be used as marker in the decision process of the timing of therapeutic CSF removal and for predicting the outcome. This relationship will be investigated from the CSF obtained from the study "Randomised PHVD treatment study: a multicentre randomised controlled trial of low versus high threshold treatment in preterm infants with progressive

posthemorrhagic ventricular dilatation", which has been started in the Netherlands since april 2006. Preterm infants with progressive PHVD will be randomised in low or high threshold group. In low threshold group the therapy will be started at moderate PHVD; in high threshold at severe PHVD. Both the therapy and the end-point of the therapy (desired ventricular size) are the same for both groups.

Study objective

1. Is the concentration of brain specific proteins in CSF higher in newborn who are treated after high threshold as compared to newborns who are treated after low threshold?
2. Is there any relationship between the concentration of brain specific proteins in CSF, glucose and lactate on the one hand and the severity of ventricular dilatation, VP drain insertion and neurodevelopmental outcome at the age of 2 year on the other hand?

Study design

CSF will be collected at day 1 and thereafter twice a week in the first 2 weeks and once in the third week after start of serial intermittent CSF removal from SCVR. Cell count, total protein, glucose, and lactate will be determined at own hospital. Brain specific proteins (S100, NSE, GFAP, NFL, MBP, Tau) will be determined in Radboud University Nijmegen Medical Centre. Simultaneously, the severity of ventricular dilatation will be assessed by cerebral ultrasound. Placement of ventriculoperitoneal drain will be registered.. Neurodevelopmental outcome at the age of 2 year will be assessed by Bayley Scales of Infant Development. The relationship between the concentration of brain specific proteins, glucose and lactate in CSF on the one hand and the therapy threshold, the severity of ventricular dilatation, VP drain insertion and neurodevelopmental outcome at the age of 2 year on the other hand will be investigated using correlation analysis.

Study burden and risks

There is no risk or burden. The CSF and the data of cerebral ultrasound and Bayley Scales of Infant Development are already available from the *Randomised PHVD treatment study*.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants (gestational age < 34 weeks) with intraventricular hemorrhage grade III and progressive post-hemorrhagic ventricular dilatation

Exclusion criteria

congenital cerebral malformation
cerebral parenchymal hemorrhage/infarction
periventricular leucomalacia
PHVD already present at birth
infection of the CNS
metabolic disorder

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	125
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL12464.091.06