Evaluation of venous hypertension in craniosynostosis

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Primary Objective: To evaluate intracranial venous haemodynamics in single suture craniosynostosis, and to determine the effect of surgery.Secondary Objective: Provide insight in the relationship between venous haemodynamics and intracranial...

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

Summary

ID

NL-OMON42060

Source
ToetsingOnline

Brief title
Evaluation of venous hypertension in craniosynostosis

Condition

- Increased intracranial pressure and hydrocephalus

Synonym
Craniosynostosis, premature closure of one or more cranial sutures

Research involving
Human

Sponsors and support

Primary sponsor: Plastische en Reconstructieve Chirurgie en Handchirurgie
Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Keyword: Craniosynostosis, Hypertension, Ultrasonography, Venous

Outcome measures

Primary outcome

The main study parameters follow from the ultrasounds. With (transcranial) colour-coded duplex sonography the diastolic, systolic and mean blood flow velocities are measured. Pulsatility and resistive index (PI and RI) will be calculated. For the individual patient the endpoint of this study is reached after the second ultrasound.

Secondary outcome

N/A

Study description

Background summary

Craniosynostosis is defined as the premature fusion of one or more cranial sutures. Although many theories have been formulated on its aetiology, definitive answers have not yet been found. One of the most important consequences of the premature fusion of cranial sutures is a higher chance of elevated intracranial pressure (ICP).
The old hypothesis stated that elevated intracranial pressure was caused by a too small intracranial volume due to the synostosis of the cranial sutures and that the elevated ICP induced the neurocognitive development impairment. Our ongoing research on this topic has proven this theory wrong: patients have a normal brain volume and a normal or enlarged intracranial volume. Our current hypothesis is that elevated ICP is mainly caused by venous hypertension and local perfusion disturbances of the brain. Additional factors that have a detrimental effect on ICP are increased cerebrospinal fluid volume and obstructive sleep apnea, but these are only of significance for patients with syndromic craniosynostosis.
To prove this theory, this study focuses on intracranial venous haemodynamics. With the use of a transcranial colour-coded sonography the haemodynamics of the superior sagittal sinus (SSS) will be evaluated and compared to a control

group. The SSS is the most important venous outflow tract for the brain. Secondly, by evaluating its haemodynamics before and after surgery the effect of our surgery on venous haemodynamics can be evaluated. Thirdly, flow measurements at the level of the jugular veins will be performed in order to assess the effect of the jugular veins on intracranial venous haemodynamics. Lastly, this study aims to analyse the relationship between venous haemodynamics and the occurrence of elevated ICP. Our standard treatment protocol evaluates patients for signs of elevated ICP. By assessing these data in relation to the venous haemodynamics measured earlier its relationship can be clarified.

Study objective

Primary Objective: To evaluate intracranial venous haemodynamics in single suture craniosynostosis, and to determine the effect of surgery.
Secondary Objective: Provide insight in the relationship between venous haemodynamics and intracranial pressure in single suture craniosynostosis.

Study design

This will be an observational study: a prospective cohort study with a (nested) case-control study.

Study burden and risks

This study proposes to perform two ultrasounds in craniosynostosis patients, before and after surgery. This does not pose any health risk to the patient. It does however take time. Performing the complete ultrasound will take approximately 30 minutes. By planning the ultrasounds together with the routine follow-up appointments patients will not need to come to the hospital solely for this study. After the second ultrasound patients will be followed according to standard treatment protocol.
Control group
The control group will consist of NSOP patients. As said earlier ultrasound does not pose any health risk to the subject. Inclusion in this study as a control implies an elongation of two regular hospital visits of 30 minutes.
Benefits
By assessing venous haemodynamics in trigonocephaly and scaphocephaly patients more insight into the pathophysiology is gained and the effect of our surgery on intracranial venous haemodynamics can be evaluated. Secondly, the role of venous haemodynamics in the occurrence of elevated ICP can be analysed. This provides us with valuable information on the possible causes of elevated ICP. By identifying these factors at an early age elevated ICP and its long term consequences can possibly be prevented. Comparison with a well-defined, representative, control group provides us with valuable information of the effect of craniosynostosis on intracranial venous haemodynamics. In current

literature such a control group is not available.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Premature synostosis of the metopic or sagittal suture.
- Presentation at the outpatient clinic before the fontanel has closed.
- Patient will be treated with surgery.

Exclusion criteria

- Closure of multiple sutures or syndrome diagnosis.

- Known with other brainmalformation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-04-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	16-03-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-06-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-12-2017
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL51185.078.14