Magnetic Resonance Imaging in patients with craniosynostosis.

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1. To assess whether microarchitectural alterations in the brain of different types of craniosynostosis patients are indeed primary.2. To assess local cerebral perfusion in craniosynostosis patients and its change after surgery.3. To understand the...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON38890

Source
ToetsingOnline

Brief title
MRI in craniosynostosis

Condition

- Other condition
- Congenital and hereditary disorders NEC

Synonym
Craniosynostosis, premature fusion of the skullsutures

Health condition

ontwikkeling van hersenen (in relatie tot het te vroeg sluiten van schedelnaden)

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Hoofdzaak

Intervention

Keyword: craniosynostosis, MRI

Outcome measures

Primary outcome

The main study parameters follow from the MR scan outcomes. The cerebral blood flow will be measured in ml/g/min per region of the brain. DTI data is expressed in fractional anisotropy (FA) and Apparent Diffusion Coefficient (ADC) values for all regions of interest.

The endpoint for the individual patient is reached after the last MR scan is made. Standard clinical follow-up will last until the patient is 18 years of age.

Secondary outcome

primary study parameters will be correlated to the outcome of neuro-cognitive test performed during standard clinical follow-up.

Study description

Background summary

Currently the focus of clinicians treating craniosynostosis is shifting from only the skull to the skull and the brain. The old hypotheses stated that elevated intracranial pressure (ICP) 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! The first studies we performed on brain

anomalies were done in 6 to 12 year old patients with syndromic craniosynostosis. Their MRI findings suggest that the observed brain anomalies are a direct result of the causative genetic mutation. Our current hypothesis is that elevated ICP is mainly is 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 hypothesis, this study focuses on the brain malformations by performing magnetic resonance (MR) scans (1.5 TESLA) with diffusion tensor imaging (DTI) and arterial spin labelling (ASL) as part of the standard MR scan protocol to visualize disturbances in the white matter of the brain and cerebral blood flow. Additionally, this study aims to find the correlation between brain imaging and brain function by combining the MRI data with the outcome of standardized neurodevelopmental tests performed according to standard treatment protocol.
By assessing these data at a young age in a broad group of craniosynostosis patients, before and after surgery, a better understanding of the condition will be achieved, which will optimize its treatment.

Study objective

1. To assess whether microarchitectural alterations in the brain of different types of craniosynostosis patients are indeed primary.
2. To assess local cerebral perfusion in craniosynostosis patients and its change after surgery.
3. To understand the relation between local brain perfusion and the occurrence of elevated ICP.

Study design

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

Study burden and risks

First of all, patients need to visit the hospital to receive their MR scans; this will take time and costs. While performing the MR scan patients will receive general anaesthesia. Given the experience of our anaesthesiologists in the childrens hospital and the safe environment in which this procedure will be performed risks remain low. However, adverse events that can occur are seen more frequently in children below one year of age than in older children, mostly concerning respiratory events or ventilation problems.
Benefits
By performing MR scans in a broad selection of craniosynostosis patients a better understanding of the underlying pathophysiology, particularly of the

elevated intracranial pressure and blood flow disturbances, will be achieved. It could well be that detectable changes in blood flow precede the occurrence of papilledema which is a late sign of elevated ICP. If this is the case, an important change of the screening method during follow-up may be advised. DTI focuses on the quality of white matter tracts in the brain and anomalies were demonstrated in our syndromic craniosynostosis patients at age 6 to 12; studying white matter quality in very young craniosynostosis patients will reveal whether or not these changes are truly inborn. By linking MRI findings with cognitive, language and motor development a better understanding of this pathophysiology is acquired and would contribute to an optimal treatment of these patients regarding counselling, type of surgery, timing of surgery and even cognitive, language and/or motor function intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Patients with one of the following diagnoses:
- Complex craniosynostosis
- Syndromic craniosynostosis
- Trigonocephaly
- Scaphocephaly
And:
- Between 0 and 2 years of age

Exclusion criteria

Patients with any metallic object in their skull.
Patients with a known allergy to the used anaesthetic agent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Not approved

Date:	15-04-2013
Application type:	First submission
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	NL43151.078.13