Optical coherence tomography in non-syndromic craniosynostosis patients

Published: 18-02-2016
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The primary objective is to obtain OCT data for children aged 4 to 10 diagnosed with non-syndromic craniosynostosis and to compare these to the normal reference values.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON43817

Source
ToetsingOnline

Brief title
OCT in non-syndromic craniosynostosis patients

Condition

- Congenital and hereditary disorders NEC
- Retina, choroid and vitreous haemorrhages and vascular disorders
- Increased intracranial pressure and hydrocephalus

Synonym
congenital disorder of the skull, craniosynostosis

Research involving
Human

Sponsors and support

Primary sponsor: Oogheelkunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Increased intracranial pressure (ICP), non-syndromic craniosynostosis, Optical Coherence Tomography (OCT), Pediatrics

Outcome measures

Primary outcome

Total retinal thickness (TRT) and the retinal nerve fiber layer thickness

(RNFL)

Secondary outcome

NVT

Study description

Background summary

Children with craniosynostosis are at risk for increased intracranial pressure(ICP), particularly during the first 6 years of life.Increased ICP is routinely determined through fundoscopy, indicated by the presence of papilledema. The drawback of fundoscopy is the fact that this is an observer dependant and qualitative method Optical coherence tomography has a high potential as a screening tool for elevated intracranial pressure in craniosynostosis. The big advantage of OCT is that it is a quantitative method which is observer-independent
In our previous study on patients with a congenital disorder of the skull (craniosynostosis), we have used OCT and found a significant difference for children with this disorder and papilledema compared to those patients without papilledema. Papilledema results from axonal stasis secondary to raised ICP. We recently established the normative reference values for children aged 4 to 10 years of age. With these data, we can compare our data from the craniosynostosis cohort and start using OCT as a tool in clinical treatment.

Study objective

The primary objective is to obtain OCT data for children aged 4 to 10 diagnosed with non-syndromic craniosynostosis and to compare these to the normal reference values.

Study design

In this cohort study, an OCT scan will be made in non-synromic craniosynostosis patients aged 4 to 10. The investigator will contact the parents by mail at least 1 week prior to their appointment. The parent will receive the patient information file and be asked for their permission to have their child participate in our study. If consent is given, the investigator will accompany the patient and parents to the OCT and take the image.
. The child has to focus on a red light for a few seconds during which the images are captured. The child*s pupils are dilated with eye drops to facilitate the image capturing with the OCT. Because dilation of the pupils is associated with some discomfort such as temporarily blurred vision, only children who*s pupils have already been dilated because of the fundoscopy for which they visit the department of Ophthalmology are asked to participate. Based on a power analysis done by a statistician we want to obtain a group of 90 children with a non-syndromic craniosynostosis. In our previous study we already collected the OCT data of 35 non-syndromic patients. We want to combine the OCT data of the newly referred participants with the already existing OCT data and compare them to the reference values we obtained in our other study. Therefore, we want to include another 55 non-syndromic patients in our study in a time period of 6 months.

Study burden and risks

The children that participate do not require additional eye drops for dilating the pupil. They only have to focus at a red light for a few seconds without blinking. The OCT doesn't cause any pain, radiation or other burden to the child. No extra hospital visit is required. As the OCT is situated at the department of Opthalmology, the extra time spend because of this measurement is very limited. This study does involve a non-therapeutic study in minors, but with negligible risks and minimal burden. The investigator is present during the investigation and will stop the procedure whenever the child's behavior requires so, according to the "Code of conduct relating to expressions of objection by minors participating in medical research".

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

children :
- aged 4 to 10 years
- diagnosed with non-syndromic craniosynostosis
- have dilated pupils because of the clinical examination (opthalmologist) for which the child is referred.

Exclusion criteria

children with behavioural problems or mental retardation resulting in a lack of concentration or instructability which is required to obtain OCT scans of usable quality.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-03-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-06-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-09-2018
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	NL55113.078.15