Retinal thickness measurement through optical coherence tomography (OCT) in children

Published: 20-06-2014
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The objective of this study is to establish normative data on OCT in children between the ages of 4 to 10.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40470

Source
ToetsingOnline

Brief title
OCT in children

Condition

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

Synonym
Retina disorder

Research involving
Human

Sponsors and support

Primary sponsor: Plastische en Reconstructieve Chirurgie en Handchirurgie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, optical coherence tomography

Outcome measures

Primary outcome

We will provide normative data on retinal layer thickness per year of age for children in between 4 to 10 years of age. The endpoint is reached when we have gathered 5 children for each age.

Secondary outcome

Not applicable

Study description

Background summary

Optical coherence tomography is a rather new method to assess the thickness of the retina. One of the applications concerns the quantification of the retinal layer thickness as a measure for increased intracranial pressure (ICP). Increased ICP is routinely determined through fundoscopy, indicated by the presence of papilledema. The drawbacks of fundoscopie is the fact that this is an observer dependant and qualitative method. The advantages of OCT are its objective measurements and quantification. However, norm data for children are lacking while these are needed for interpretation of data obtained in children with disorders that affect the retinal layer.

Study objective

The objective of this study is to establish normative data on OCT in children between the ages of 4 to 10.

Study design

From an earlier study in children with craniosynostosis we experienced that obtaining an OCT measurement in children from the age of 4 years is very feasible. The OCT uses near infrared light which is able to penetrate tissue without causing damage and is thus able to measure the thickness of the retinal layer. 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 clinical indication for which they visit the department of Ophthalmology are asked to participate.
A child that wants to participate and whose parents have given consent will be asked to place the head on a headrest and focus on a red light for a few seconds without blinking.

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 Ophthalmology, 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 behaviour 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

- Aged 4 to 10 years of age
- Have dilated pupils because of the clinical examination for which the child is referred

Exclusion criteria

A condition that is likely to affect retinal layer thickness will be an exclusion criterium.

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):	23-06-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2014
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	NL47389.078.14