Macular Retinal Thickness and Retinal Nerve Fiber Layer Thickness Measured in Amblyopia, an OCT study.

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1.To investigate the relationship between amblyopia and the development of the neurosensory retina:Measurements: Central / foveal retinal thickness RNFL Inner retinal layer thickness thru segmentation algorithms 2.To investigate the differences in...

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

Summary

ID

NL-OMON31038

Source
ToetsingOnline

Brief title
AmblyOCT

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
amblyopia, lazy eye

Research involving
Human

Sponsors and support

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

Intervention

Keyword: amblyopia, OCT, pathophysiology

Outcome measures

Primary outcome

* Visus

* Etiology amblyopia

* OCT measurements (outlined in appendix C of the protocol)

Secondary outcome

* Refraction

* Stereopsis

* As-length

* Age

Study description

Background summary

Amblyopia is defined as a unilateral or bilateral decrease of visual acuity caused by pattern vision deprivation or abnormal binocular interaction during the critical period of visual development for which no optical or organic origin can be detected (von Noorden 1996). Amblyopia can be seen as a developmental disorder; the same causal factors that cause amblyopia during infancy or early childhood have no lasting effect on vision when these occur in adulthood.
Retinal involvement accompanying amblyopia is however controversial. In the normal developing retina a process of postnatal ganglion cell reduction occurs (referentie). In amblyopia this process is thought to be disrupted due to unequal or unfocussed images, projected on the retina.
Optical Coherence Tomography (OCT) is a relatively new imaging technique, similar to ultrasonography, which uses near-infrared light waves, instead of ultrasound, to obtain a reflectivity profile of the retina (Huang et al., 1991). OCT is widely used for imaging the vitreoretinal interface, for monitoring macular edema and retinal thickness, retinal nerve fiber layer

(RNFL) thickness and optic nerve head parameters in a wide variety of patients. The OCT technique currently available in clinical practice is also referred to as time-domain OCT (TDOCT). Only recently, major advances in imaging speed, sensitivity and image resolution have been achieved with the introduction of spectral-domain OCT (SDOCT) (Nassif et al.2004; Wojtkowski et al., 2004). Moreover, OCT is a non-invasive, non-contact, and was found to be well tolerated and easy to undergo by children (Shields et al. 2006). .
Yen et al. (2004) studied the retinal thickness using OCT in two groups of amblyopes, one group contained strabismic amblyopes while the other contained anisometropic amblyopes. They found a significant thicker RNFL in anisometropic amblyopes, compared to the fellow eyes. This was not the case in the group of strabismic amblyopes. These study outcomes are refuted by Repka et al. who studied a similar population of patients and found no clinical difference in OCT measured RNFL thickness. Huynh et al. (2007) investigated the macular and peripapillary RNFL thickness in amblyopia. They found an increased foveal minimum thickness in amblyopic eyes compared to the normal fellow eye and compared to eyes of non-amblyopic children. Children who had untreated unilateral amblyopia had a significantly increased inter-ocular difference in central macular thickness. No differences in peripapillary RNFL thickness were found in amblyopic eyes compared to normal eyes.
Retinal involvement remains controversial in strabismic and anisometropic amblyopes. Therefore the topic of this study is to investigate the macular retinal thickness and the RNFL thickness in both strabismic and anisometropic amblyopic patients, using both TDOCT and SDOCT, and compare them with a control group of normal subjects. We hypothesize that there is a correlation between the causal factors of amblyopia and a normal postnatal reduction of the inner neuroretinal layers in the development of the visual pathway. One would expect a thicker macular and RNFL thickness in amblyopic eyes compared to healthy subjects, but this is still poorly investigated.

Study objective

1.To investigate the relationship between amblyopia and the development of the neurosensory retina:
Measurements: Central / foveal retinal thickness
RNFL
Inner retinal layer thickness thru segmentation algorithms
2.To investigate the differences in macular retinal and/or RNFL thickness between strabismic and anisometropic amblyopes

Study design

This study is designed as a prospective, cross sectional case-control study. Our control group consist of healthy children with no ophthalmic or orthoptic diagnosis. In theory the non amblyopic eye could be used as a control. This is however questionable because it is unknown what the effect of the amblyopic eye

will have on development of the normal eye. By choosing normal, healthy subjects as a control group this issue is avoided.

Study burden and risks

The patient will undergo a single IOL and OCT measurement during 35 minutes, directly afterwards the normal orthopthic examination.
OCT and IOL master use very low levels of energie, so the patient (eye) is not at any risk. Moreover, OCT is a non-invasive, non-contact, and was found to be well tolerated and easy to undergo by children (Shields et al. 2006).

Time table per patient: outlined in appendix C, page 9 of the protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

*diagnosed amblyopia caused by an anisometropia, strabismus or a combination of these two who received therapy with a visual acuity difference of two lines between the two eyes.
*The patient has to be at least three years old and cooperative enough to sit through all examination, including the OCT examination.
*Refractive error within the range of S+12.0 and S-12.0 due to the limitations of the OCT device.
*A patient needs to have at least a 2 diopter spherical difference in refraction between both eyes and/or a 2 diopter astigmatic difference to be part of the anisometropic group.
*Patients with any manifest ocular deviation or eccentric fixation will be included in the strabismic group.
*To be part of the normal group, the patient needs to have a straight eye position, but phorias are allowed. The refraction needs to be similar in both eyes and should not be above S+5.0 or S-8.0, astigmatism should not exceed 2 diopters

Exclusion criteria

*Patients with a history of organic eye diseases or a history of intraocular surgery.
*Patients with a history of cataract or existing cataract
*Patients with retinal disorders, glaucoma or laser treatment in the preceding years.

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:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007

Enrollment:	130
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL18354.018.07