Comparison of the retinal thickness and retinal nerve fibre layer thickness using HD-OCT between treated and untreated children with anisometropic or strabismic amblyopia in comparison to healthy eyes.

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The primary objective of this study is:- To determine the potential difference in MT and RNFLT between treated and untreated patients with anisometropic or strabismic amblyopia.
Secondary objectives are:- To determine the potential differences in MT...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42678

Source
ToetsingOnline

Brief title
Comparison of MT and RNFLT between treated and untreated amblyopic children

Condition

- Vision disorders

Synonym
Amblyopia

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Vanuit het ziekenhuis

Intervention

Keyword: Amblyopia, OCT, Retinal thickness

Outcome measures

Primary outcome

H*1a: There is no difference in the MT of treated and untreated patients and the fellow eye of the treated patient with anisometropic or strabismic amblyopia.

H*1b: There is no difference in the peripapillary RNFL of treated and untreated patients and the fellow eye of the treated patient with anisometropic or strabismic amblyopia.

H*2a: There is no difference in the MT of untreated patients with anisometropic or strabismic amblyopia compared to the MT of their fellow eye and healthy right eyes.

H*2b: There is no difference in the peripapillary RNFLT of untreated patients with anisometropic or strabismic amblyopia compared to the peripapillary RNFLT of their fellow eye and healthy right eyes.

H*3a: The macula of untreated patients with anisometropic or strabismic amblyopia is thicker than the macula of their fellow eye and healthy right eyes.

H*3b: The peripapillary RNFL of untreated patients with anisometropic or strabismic amblyopia is thicker than the peripapillary RNFL of their fellow eye

and healthy right eyes.

H*4a: The peripapillary RNFL of the fellow eye in untreated and treated patients with anisometropic or strabismic amblyopia is thicker than the peripapillary RNFL of healthy right eyes.

H*4b: The macula of the fellow eye in untreated and treated patients with anisometropic or strabismic amblyopia is thicker than the macula of healthy right eyes.

Secondary outcome

not applicable

Study description

Background summary

Amblyopia is defined as the condition in which reduced visual function, caused by reduced binocular interactions and visual deprivation during the critical period, exists despite full optical correction and absence of observable ocular pathology (Barrett et al. 2004; von Noorden, 2002, p246). From previous research (Hess, 2010 and Barnes et al, 2010) we know that amblyopia causes structural changes in the lateral geniculate nucleus (LGN) and primary visual cortex. However, there is less certainty about whether this also affects the retinal development regarding macular retinal thickness (MT) and peripapillary retinal nerve fibre layer thickness (RNFLT).
In the past decade, optical coherence tomography (OCT) has been frequently used to study the effects of amblyopia on the MT and RNFLT. Yen et al, (2004) found a positive correlation between anisometropic amblyopia and RNFLT and hypothesized that this is due to slowing down the normal postnatal apoptosis of ganglion cells. Huyng et al, (2009) published the results of the Sydney Childhood Eye Study comparing MT and RNFLT in 48 strabismic and anisometropic amblyopic subjects and 3185 non-amblyopic subjects with use of the StratusOCT. In contrast with the study of Yen et al, (2004) they found no significant differences in RNFLT. However, they did find a significant larger foveal minimum thickness in amblyopic eyes compared to the normal fellow eye and the right eye of non-amblyopic children, respectively 5µm and 10µm ($p<0.05$). Also, a second comparison was made between 33 treated and 12 untreated amblyopes. Here the MT and RNFLT seemed to be larger in the untreated group, but due to a

small sample no significant difference was obtained. In line with this, a study of Al-Haddad et al, (2011) revealed similar results of MT and RNFLT using SD-OCT in amblyopic children. They compared 14 strabismic, 31 anisometropic and 20 non-amblyopic anisometropic children and found no significant differences in the RNFLT. In contrast, the MT in anisometropic amblyopes was significantly thicker compared to non-amblyopic anisometropic children, however this difference was not found in the strabismic group. Wu et al, (2013) did find a significant thicker RNFL in 72 hyperopic anisometropic amblyopes. The amblyopic eye was compared with the fellow eye. Miki et al, (2010) studied the RNFLT using StratusOCT in 25 patients with recovered amblyopia and 26 patients with persistent amblyopia, to establish if differences in RNFLT are associated with persistent amblyopia. No differentiation was made on the type of amblyopia. There were no significant changes found in RNFLT between the two groups.
To conclude, there is increasing scope of literature on the subject, but there are still conflicting results regarding the impairment of the MT and RNFLT in strabismic and anisometropic amblyopic subjects. These results may be due to small sample sizes, not using a non-amblyopic control group, use of different instruments, and by not separating the strabismic and anisometropic amblyopes. Furthermore, there is almost no literature available about the possible changes in MT and RNFLT after amblyopia therapy in amblyopic children. So it is not clear whether occlusion therapy affect the development of the retina and if changes occur in the MT and RNFLT.
The purpose of the study is to examine the MT and RNFLT in both untreated and treated patients with either anisometropic or strabismic amblyopia. Furthermore, untreated and treated amblyopic patients will be compared with non-amblyopic controls to find out if the retina of an untreated and treated amblyopic patient show differences with that of a healthy non-amblyopic subject. If the differences in MT and RNFLT in the amblyopic eye before and after occlusion therapy are known, there will be a better understanding of retinal level why visual acuity improves and a better prognosis can be given.

H1a: The macula of treated patients with anisometropic or strabismic amblyopia is thinner than the macula of untreated patients.
H1b: The peripapillary RNFL of treated patients with anisometropic or strabismic amblyopia is thinner than the peripapillary RNFL of untreated patients.
H2a: The macula of untreated patients with anisometropic or strabismic amblyopia is thicker than their fellow eye and the macula of the right eye of healthy eyes.
H2b: The peripapillary RNFL of untreated patients with anisometropic or strabismic amblyopia is thicker than the peripapillary RNFL of their fellow eye and the right eye of healthy eyes.
H3a: There is no difference in macular thickness between treated patients with anisometropic or strabismic amblyopia, their fellow eye and healthy right eyes.
H3b: There is no difference in peripapillary RNFL thickness between treated patients with anisometropic or strabismic amblyopia, their fellow eye and healthy right eyes.

H4a: There is no difference in macular thickness between the fellow eye of untreated and treated patients with anisometropic or strabismic amblyopia and healty right eyes.
H4b: There is no difference in peripapillary RNFL thickness between the fellow eye of untreated and treated patients with anisometropic or strabismic amblyopia and healty right eyes.

Study objective

The primary objective of this study is:
- To determine the potential difference in MT and RNFLT between treated and untreated patients with anisometropic or strabismic amblyopia.
Secondary objectives are:
- To determine the potential differences in MT and RNFLT in the untreated and treated patient with anisometropic or stabismic amblyopia compared with normal healthy right eyes.
- To determine the potential differences in MT and RNFLT in the fellow eye of the treated and untreated patients with anisometropic or strabismic amblyopia.
- To determine the potential differences in MT and RNFLT in the untreated patient with anisometropic or stabismic amblyopia and their fellow eye.
- To determine the potential differences in MT and RNFLT in the treated patient with anisometropic or stabismic amblyopia and their fellow eye.
- To determine the the potential differences in MT and RNFLT in the fellow eyes of the amblyopic patients and normal healthy right eyes.

Study design

Observational cross-sectional study.

Study burden and risks

Participation in the study is voluntary and has no direct benefits for the patient. The main disadvantage regarding the OCT scan is the little extra time, but it is also possible, but unlikely, that an unexpected abnormality in the retina of the patient is detected. In the case that an abnormality is detected, the parents will be directly informed and their child will be referred to an ophthalmologist and will be withdrawn from the research.
The cyclopentolate eye drops will be used in the standard orthoptic investigation, regardless the need for an additional OCT examination. These drops are frequently used and the side effects are known to be minimal (Farmaceutisch kompas, 2015). All the OCT measurements are non-invasive and not harmful for the eyes of the child. Therefore the risks are considered negligible and the burden for the patient is minimal.
Future patients benefit from the results, because more insight is obtained of the development and possible structural changes in the layers of the retina

after amblyopia treatment in two types of amblyopic patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet the following criteria:;Children cooperative for OCT examination.
The refraction error must be within the range of -20 to +20 diopters due to limitations of the OCT device.;Untreated strabismic and anisometropic amblyopes:
Within the age range of three to six years.
With at least a two line visual acuity difference between the amblyopic and the fellow eye.
Teated strabismic and anisometropic amblyopes:
Within the age range of seven to twelve years.
With equal (1.0 snellen) or nearly equal visual acuity, no more than one line difference.
With at least a two line visual acuity difference between the amblyopic and the fellow eye

before treatment.
Treated as well as untreated anisometropic amblyopes need to have a difference in refraction error of at least 1 diopter spherical and/or 1 diopter astigmatic difference. ;Age matched controls:
Are orthotropic or have a slight phoria on cover testing with quick recovery
Have a similar refraction error, spherical and/or astigmatism of no more than 0,75 diopters.

Exclusion criteria

- Patients with a systemic disease or ophthalmic disease.
- Infants born at <32 weeks post conception.
- Infants with ROP.
- Patients with nystagmus or eccentric fixation.

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):	02-03-2016
Enrollment:	360
Type:	Actual

Ethics review

Approved WMO

Date:	19-01-2016

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL55299.091.15