Effect of optical density filters on retinal nerve fiber layer and macular inner retinal layer thickness measurements using spectral domain optical coherence tomography

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The purpose of this study is to identify and quantify the influence of medium opacity on RNFL and inner retinal layer thickness measurements using SD-OCT, as well as the effect of cataract on the filter measurements. Also to evaluate the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON39167

Source
ToetsingOnline

Brief title
OCT image quality

Condition

- Other condition
- Glaucoma and ocular hypertension

Synonym
glaucoma, ocular hypertension

Health condition

oogaandoeningen, staar

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cataract, Glaucoma, Optical coherence tomography, Retinal nerve fiber layer

Outcome measures

Primary outcome

The amount of measured layer thickness decrease in retinal layer thickness measurements, induced by the increase in optical density of the artificial filters.

The relationship between the underestimation of the retinal layer thicknesses and the optical density of the artificial filters.

The relationship between these filter measurements before and after cataract surgery.

The difference in measured RNFL thickness between volume scans and peripapillary circle scans of the optic nerve head.

Secondary outcome

NA

Study description

Background summary

Optical coherence tomography (OCT) is an objective imaging technique, based on coherence interferometry.1 Spectral domain (SD) OCT, also known as Fourier

Domain OCT, allows fast acquisition of images with high resolution, and with SD-OCT one can make very accurate measurements
OCT is non-invasive technique and just lightly burdensome for patients. It only takes a few seconds to acquire the images and the whole procedure takes a few minutes, dependant on the amount of scans required.

Retinal nerve fiber layer (RNFL) thickness measurements are one of the OCT measurements that have shown good reproducibility and good diagnostic abilities for the diagnosis of primary open angle glaucoma. Thickness measurement of the macular inner retinal layer in the macular region has also shown promise as diagnostic measurement for the detection of glaucoma.

Previous studies have demonstrated that RNFL thickness measurements are influenced by cataract. A linear relationship has been described between OCT-equivalent optical density of cataract and underestimation of RNFL thickness measured with OCT.

We aim to identify and quantify the influence of artificial filters with a predefined optical density on retinal nerve fiber layer (RNFL) measurements, and inner retinal layers using spectral domain optical coherence tomography (SD-OCT), as well as the effect of cataract on the filter measurements.

RNFL thickness measurements with SD-OCT can be done using different scan protocols. Most SD-OCT instruments feature a 3D data set protocol and circular scan protocol. We intend to evaluate the reproducibility and agreement of two SD-OCT scan protocols for RNFL thickness layer measurements.

Study objective

The purpose of this study is to identify and quantify the influence of medium opacity on RNFL and inner retinal layer thickness measurements using SD-OCT, as well as the effect of cataract on the filter measurements.

Also to evaluate the reproducibility and agreement of two different SD-OCT scan protocols for RNFL thickness layer measurements

Study design

A cross sectional study involving healthy subjects, glaucoma and cataract patients

Study burden and risks

Participants of this study will not be exposed to invasive methods. The study will require time of the patients. Furthermore mydriatic drops will be instilled that can temporarily cause a slight decrease in vision. In rare cases

an allergic reaction can occur, which can temporarily cause redness of the eye.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria healthy volunteers
* Willing and able to sign the informed consent, after reading the information form
* No history of ophthalmological disease;Glaucoma patients:
* Willing and able to sign the informed consent, after reading the information form
* Diagnosed with primary open angle glaucoma;Cataract patients:
* Willing and able to sign the informed consent, after reading the information form
* Diagnosed with cataract and eligible for cataract surgery

Exclusion criteria

For healthy volunteers and glaucoma patients
* Media opacities, like cataract, that will make it impossible to make reliable images with the OCT
* Hypermetropia more than S+5 dioptres, or myopia more than S-8 dioptres
* Presence of diseases including retinal disorders that may influence visual acuity, visual field testing or the results of structural measurements done by SD-OCT;For cataract patients:
* Media opacities other than cataract, that will make it impossible to make reliable images with the OCT
* Hypermetropia more than S+5 dioptres, or myopia more than S-8 dioptres
* Presence of other diseases including retinal disorders that may influence visual acuity, visual field testing or the results of structural measurements done by SD-OCT

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2013
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	25-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	31-07-2013
Application type:	Amendment
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	NL40286.018.12