Clinical significance of new OCT parameters in diagnosis and follow-up of primary open angle glaucoma

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We want to assess the diagnostic performance of retinal nerve fiber layer (RNFL) thickness, macular ganglion cell layer (GCL) thickness, lamina cribrosa thickness and choroid thickness around the optic disc measured with SD-OCT in differentiating...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON37906

Source
ToetsingOnline

Brief title
GLOCT

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma, ocular hypertension

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Glaucoma, Optical Coherence Tomography

Outcome measures

Primary outcome

Sensitivity and specificity of the new SD-OCT parameters will be compare with the sensitivity and specificity of the RNFL thickness measurements and the visual field testing. We will investigate to what extent these new parameters can contribute in differentiating patients from healthy controls, between stages of glaucoma, between patients with a normal and an elevated baseline IOP, and to establish the accuracy to detect progression of glaucoma.

Secondary outcome

- visual acuity

- intra ocular pressure

- visual field test outcome

- RNFL thickness

- GCL thickness

- lamina cribrosa thickness

- peripapillary choroid thickness

Study description

Background summary

Primary open angle glaucoma (POAG) is a gradually progressive optic neuropathy, resulting in irreversible visual field loss. POAG is accompanied by dysfunction and apoptosis of retinal ganglion cells, whose axons make up most of the retinal nerve fibre layer (RNFL). The standard test for progression, on which

most treatment decisions are based, is the VF examination. A disadvantage of VF testing is the fact that it is subjective, and is not particular sensitive for the earliest changes in glaucoma.

Optical Coherence Tomography (OCT) is an objective imaging technique, based on coherence interferometry. 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.

Studies have shown that RNFL measurements are highly correlated with visual function. More importantly it has been demonstrated that up to 25 to 35 % of RNFL thickness is lost before visual field (VF) defects can be detected.(1) It is estimated that this so called pre-perimetric phase can last up to 5 years.

Recently some new measurements with SD-OCT have been investigated that show promise in the diagnostic evaluation of glaucoma patients. These are thickness measurements of the ganglion cell layer, the lamina cribrosa and the peripapillary choroid.

It is relevant for clinical practice to determine how these new structural SD-OCT measurements, either as single measurement or in combination, perform in the diagnosis of different stages of POAG, compared to functional testing. Also relevant is to know how these measurements differentiate between glaucoma patients with a normal and with an elevated baseline IOP, and how sensitive these measurements are to detect progression over time.

Study objective

We want to assess the diagnostic performance of retinal nerve fiber layer (RNFL) thickness, macular ganglion cell layer (GCL) thickness, lamina cribrosa thickness and choroid thickness around the optic disc measured with SD-OCT in differentiating patients from healthy controls, between stages of glaucoma, between patients with a normal and an elevated baseline IOP, and to establish the accuracy to detect progression of glaucoma.
The new parameters could add to an improved, earlier diagnosis of glaucoma, and shed light on the pathophysiologic differences between patients with a normal or higher baseline eye pressure.

Study design

This study is a multicenter cross-sectional and follow up study involving glaucoma patients and healthy subjects.

After signing informed consent, participating patients will be included in each of the following categories, based on the Hodapp classification: ocular hypertension, suspect glaucoma, early glaucoma and moderate glaucoma.

Based on intra ocular pressure (IOP) day curves before any kind of treatment, patients in each of the glaucoma category will also be divided in subgroups of normal tension glaucoma and high pressure glaucoma. For baseline IOP the highest documented IOP without treatment is taken.
All patients and healthy controls will undergo a complete ophthalmologic examination, including best-corrected visual acuity, eye pressure measurement and slit-lamp examination, including gonioscopy.
RNFL thickness, GCL thickness, lamina cribrosa, and peripapillary choroid thickness will be measured using SD-OCT (Spectralis, Heidelberg). Visual field testing will be performed using the Humphrey Field Analyzer (HFA), Swedish Interactive Thresholding Algorithm (SITA) standard 24-2 perimetry. Age, gender, family history of glaucoma, duration of ocular hypertension, suspect or other category of glaucoma will be recorded.

Study burden and risks

Participants of this study will not be exposed to invasive methods. The study will require more time of patients than a regular check-up. 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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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients with ocular hypertension, suspect glaucoma, early glaucoma and moderate glaucoma, 18 years of age or older
• Patients with open anterior chamber angle
• VA > 20/30
• Able to perform reliable visual field test
• Willing and able to sign the informed consent.

Exclusion criteria

• 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-7 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
• Presence of signs of secondary glaucoma such as inflammatory or neovascular causes, with the exception of pigment dispersion syndrome and pseudoexfoliation syndrome

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2012
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO

Date:	25-07-2012
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	NL39425.018.12