Structural and functional measurements for glaucoma detection and monitoring in early, moderate and advanced glaucoma

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to evaluate the functional and structural measurements for glaucoma detection and monitoring at different stages of the disease.

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

Summary

ID

NL-OMON45325

Source
ToetsingOnline

Brief title
Glaucoma detection & monitoring

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Glaucoomfonds;Stichting Oogfonds Nederland;Stichting voor Ooglijders

Intervention

Keyword: Function, Glaucoma, Structure

Outcome measures

Primary outcome

Structural and functional measurements

Secondary outcome

See protocol

Study description

Background summary

The use of structural measurements from imaging devices and functional measurements from perimetry for the detection and monitoring of glaucoma remains a topic of great interest in current scientific research. There is no consensus on what measurement technique or combination of techniques is best used for the detection of glaucoma and the monitoring of the disease in the early, moderate and advanced stages of glaucoma. This is partly because comparing these different measurements techniques in the different stages of glaucoma is difficult because they measure different quantities, expressed by different units. Furthermore, there is sufficient evidence that the correlation between structural and functional measurements is poor. This poor correlation has several causes, such as measurement noise and differences in measurement variability and bandwidth between the various measurements techniques in the different stages of glaucoma. A comparison of the performance of each measurement technique for the different stages of glaucoma would enable us to select the optimal technique for both the detection and monitoring of glaucoma, and thereby further improve our clinical management of glaucoma.

Study objective

to evaluate the functional and structural measurements for glaucoma detection and monitoring at different stages of the disease.

Study design

Observational cross-sectional and longitudinal cohort-study

Study burden and risks

Imaging with commercially available low-luminance ophthalmic camera*s and scanning devices, functional testing with standard perimetry (usual care), measurements of intraocular pressure (usual care). Added burden will be 0.5-1.5 hour per annum for patients with glaucoma and 1.5-2.0 hours per annum for healthy controls. No risks.

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
Rotterdam 3011 BH
NL
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
Rotterdam 3011 BH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age >= 40 years and < 80 years
Informed consent

BCVA of 0.3 or better (LogMAR)
Refractive error between -10.0 to +5.0 D range
(See section 4.2 of the protocol).

Exclusion criteria

Ophthalmic:
Cataract surgery in previous 12 months
Previous refractive or vitreoretinal surgery.
Diabetic retinopathy, diabetic macular oedema, or other vitreo-retinal disease
Corneal defects
Previous keratoplastic surgery.
Systemic:
Diabetes, leukaemia, AIDS, uncontrolled hypertension, multiple sclerosis (MS) or life threatening disease.

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:	Pending
Start date (anticipated):	01-03-2017
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO Date:	16-02-2017
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	NL60260.078.16