Polarization-sensitive optical coherence tomography for imaging of the retinal nerve fiber layer

Published: 14-02-2017 Last updated: 11-04-2024

To assess polarization-related RNFL characteristics of normal and glaucomatous eyes, and to explore the perspective of PS-OCT for other ocular conditions.

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

Summary

ID

NL-OMON45625

Source ToetsingOnline

Brief title The RNFL on PS-OCT

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 Wetenschappelijk Onderzoek

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Oogziekenhuis & Rotterdamse Stichting Blindenbelangen

Intervention

Keyword: OCT, polarization, retinal tissue layers

Outcome measures

Primary outcome

Birefringence and retardation of RNFL.

Secondary outcome

Age, gender etc.

Study description

Background summary

The retinal nerve fiber layer (RNFL) has unique polarization properties which can be measured and quantified by polarization sensitive OCT (PS-OCT). These properties are induced by the microtubules in the ganglion cell axons. It is hypothesized that the microtubule density is related to the RNFL*s health and is affected in glaucoma before actual thinning of the RNFL occurs. Measuring polarization properties of the RNFL could therefore provide information on glaucomatous damage at an early stage. Polarization characteristics of other retinal tissue will be explored for various ocular conditions as well.

Study objective

To assess polarization-related RNFL characteristics of normal and glaucomatous eyes, and to explore the perspective of PS-OCT for other ocular conditions.

Study design

Prospective, observational.

Study burden and risks

Inconvenience is minimal and risks are considered to be negligible. Study-related extra time for glaucoma patients and healthy volunteers is 20 minutes, and 40 minutes for patients with other ocular conditions.

Contacts

Public Oogziekenhuis Rotterdam

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Informed consent Age * 18 years

Exclusion criteria

Healthy volunteers:

- Any ocular morbidity except correction of refractive error (CoRE).

Glaucoma patients:

- Any ocular morbidity except CoRE or glaucoma.

Patients with other ocular condition:

- Glaucoma.

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- Obstruction of optical pathway (e.g. severe cataract).

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):	07-06-2017
Enrollment:	250
Туре:	Actual

Ethics review

Approved WMO	
Date:	14-02-2017
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.

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Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

ССМО

ID NL60255.078.16