Polarization Sensitive Optical coherence tomography-study

Published: 25-05-2021 Last updated: 05-04-2024

• In this pilot study, PS-OCT is used to image differences in fibrillary ocular structures associated with disease in patients with glaucoma, high myopia, exudative age-related macular degeneration with a suspicion of subretinal fibrosis and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular structural change, deposit and degeneration NEC
Study type	Observational non invasive

Summary

ID

NL-OMON52150

Source ToetsingOnline

Brief title PSO

Condition

• Ocular structural change, deposit and degeneration NEC

Synonym fibrillary ocular structures

Research involving Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W,Heidelberg Engineering GmbH

Intervention

Keyword: birefringence, fiber orientation, peripapillary sclera, polarization-sensitive optical coherence tomography (OCT)

Outcome measures

Primary outcome

1) quantification of the amount of variability in fibrosis measurements

calculated from PS-OCT images; the standard deviation of fibrosis volume

measurement needs to be measured within one session in several patients to

determine the sample size and expectations of future research to measure

fibrosis growth.

2) A change to the scleral retinal ring layer around the optic nerve head in

myopia and glaucoma patients when compared to nearly age/sex-matched healthy

volunteers.

3) Measuring the orientation of collagen in the peripapillary sclera in OI patients.

Secondary outcome

Secondary outcome measures are:

Current diagnostics tools (visual acuity, slit-lamp examination/biomicroscopy, fundusphotography, standard OCT, eye pressure, axial measurement) General quality metrics for PS-OCT scans by calculating feature signal-to-noise ratio and the useful signal penetration depth in the sclera for patients and healthy volunteers.

Study description

Background summary

In ophthalmology the conventional spectral domain optical coherence tomography (SD-OCT) has become indispensable to examine the retina and optic nerve head. Recently a prototype was constructed of an integrated polarization-sensitive optical coherence tomography (PS-OCT) system. This device is expected to add a new diagnostic dimension with the visualization of changes in retardation in fibrillary structures of the eye, like the retinal nerve fiber layer (RNFL), the (peripapillary) sclera, and in subretinal fibrosis associated with wet age-related macular degeneration (wAMD).

Study objective

In this pilot study, PS-OCT is used to image differences in fibrillary ocular structures associated with disease in patients with glaucoma, high myopia, exudative age-related macular degeneration with a suspicion of subretinal fibrosis and osteogenesis imperfecta (OI) patients. This will be done by quantifying the amount of system-induced variability in fibrosis measurements, and differences in the size of the sclera around the optic nerve head caused by high myopia and glaucoma patients when compared to nearly age/sex-matched healthy volunteers. For patients suffering from osteogenesis imperfeca (OI) the presence of the circularly oriented scleral collagen layer will be measured.
This study also aims to use collected data to establish quality metrics applicable to PS-OCT scans.

Study design

This is an exploratory study in which PS-OCT measurements will be performed. The participants will undergo, after reading and signing of an informed consent, standard clinical examinations and an examination with the PS-OCT system. Examination with the PS-OCT will take around an hour. Using the PS-OCT system, fibrillary structures in the eyes are visualized based on the reflectivity for orthogonal polarization states in the wavelength range of 1010 to 1110 nm.

Study burden and risks

This is a study, with minimal burden to the participants. The treatment and treatment duration will not be affected. This study forms a step towards the establishment of biomarkers of ocular diseases associated with changes in fibrillary structure and the monitoring of these diseases. The results of this study can be used to investigate and improve PS-OCT in vivo.

Contacts

Public Vrije Universiteit Medisch Centrum

De Boelelaan 1118 Amsterdam 1081HZ NL **Scientific** Vrije Universiteit Medisch Centrum

De Boelelaan 1118 Amsterdam 1081HZ NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Patients with glaucoma, high myopia or exudative AMD
- Healthy participants
- 18 years of age or older
- Willing and able to sign the informed consent, after reading the patient information form

• Able to maneuver into the ophthalmic devices (in case of wheelchair-bound type III patients)

• OI patients need to be accompanied by a friend or family member during their visit

Exclusion criteria

- Media opacities, like cataract, causing unreliable images with the PS-OCT
- Any ocular disease (outside glaucoma/myopia/exudative AMD) with possible influence on ocular fibrillary structures
- Recent (< 3 months) ocular surgery

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):	05-08-2021
Enrollment:	112
Туре:	Actual

Medical products/devices used

Generic name:	polarization-sensitive optical coherence tomography device;Heidelberg Spectralis OCT
Registration:	No

Ethics review

Approved WMO	
Date:	25-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	03-02-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-07-2022
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 CCMO

ID NL77059.029.21