Phase-resolved Optical Coherence Tomography study.

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A comparison of the PR-OCT and conventional ways of examination of patients, being slitlamp biomicrsocopy combined with stand alone SD-OCT, and fluorescein / ICG angiography, or glaucoma screening.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular haemorrhages and vascular disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON41882

Source
ToetsingOnline

Brief title
PRO-study

Condition

- Ocular haemorrhages and vascular disorders NEC

Synonym
Medical Retina Pathology and Glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Uitzicht;oogheelkundig fonds

Intervention

Keyword: Doppler-OCT, OCT-Angiography, Optical Coherence tomography, Polarisation sensitive OCT

Outcome measures

Primary outcome

Outcome parameter(s) PR-OCT

Added value of PR-OCT compared to conventional procedure(s)

Sensitivity / specificity detection of pathology compared to conventional

procedure(s)

Secondary outcome

Outcome parameters PR-OCT

• Duration of procedure

• Quality of images

• Patients* experience of comfort degree

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 Phase Resolved-optical coherence tomograph (PR-OCT). This device is expected to improve the visualisation of retinal pathology, adding detailed images of the retinal and choroidal vasculature, and of retardation differences in parts of the retina, like the RPE and the RNFL, and subretinal fibrosis, as can be seen in wet Age related Macular Degeneration.

Study objective

A comparison of the PR-OCT and conventional ways of examination of patients, being slitlamp biomicrsocopy combined with stand alone SD-OCT, and fluorescein

/ ICG angiography, or glaucoma screening.

Study design

Prospective observational (pilot) study; Evaluation of a diagnostic procedure.

Study burden and risks

Because the PR-OCT is a prototype, there is not yet a CE-marking. Though, the PR-OCT meets all the safety requirements. The light intensity during the procedure is comparable with the conventional SD-OCT and slit-lamp biomicroscopy. The device also meets the electrical safety requirements. Patients already scheduled for angiography will not experience additonal discomfort or risks.
Patients without this indication, and healthy volunteers, will recieve mydratic eye drops, these drops can be, very temporarely, mildly irritating, and will lead to blurring of vision for a few hours.

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

Healthy subjects, without any known ocular diseae / pathology, or general disesase known to influence retinal vessels and / or the neuroretina.
Patients with an indication for FA and / or ICG angiography, in particular with wet Age related Macular Degeneration, Diabetic Retinopathy, Retinal vascular occlusions, Central Serous Chorioretinopathy.
Patients with ocular hypertension or glaucoma.
Age 18 years or older.
Willing and able o sign informed consent

Exclusion criteria

Ocular spherical equivalent > +5D or < -8 D
Ocular media opacities preventing good quality images

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2017
Enrollment:	175

Type:	Actual

Ethics review

Approved WMO Date:	02-09-2015
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	NL51324.029.15