The exploratory use of an experimental flow-OCT instrument in chorioretinal diseases

Published: 17-03-2016
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To explore and optimize the usability of Doppler-OCT scanning of conditions affecting any of the retino-choroidal layers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43985

Source
ToetsingOnline

Brief title
Exploratory use of experimental flow-OCT

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
chorioretinal diseases

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis - SWOO.

Intervention

Keyword: chorioretinal diseases, diagnostics, Doppler-OCT, non-invasive

Outcome measures

Primary outcome

Hypotheses for further studies (ptotocol 8.1).

Secondary outcome

See paragraph 8.1 of the protocol.

Study description

Background summary

Optical Coherence Tomography (OCT) has become the dominant imaging modality for the posterior eye. New developments, such as the analysis of phase shifts in the reflected light from the retina to determine depth-resolved blood flow (Doppler-OCT), appear to be a promising way towards improved diagnostics for a wide range of ophthalmic conditions.

Study objective

To explore and optimize the usability of Doppler-OCT scanning of conditions affecting any of the retino-choroidal layers.

Study design

Exploratory, observational.

Study burden and risks

Risks are negligible, inconvenience is minimal. Participants do not benefit. A study-related visit lasts maximally 30 minutes.

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

Age > 18 yrs.
Informed consent.
The subject must either have no known chorioretinal pathologies (healthy volunteers) or an ophthalmic disease that affects the perfusion or blood flow in the retina or the choroid.

Exclusion criteria

Pupil size (dim ambient light) < 3.0 mm.

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):	19-05-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-06-2016
Application type:	Amendment
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	NL55220.078.15