High resolution 1050 nm wavelength centered spectral domain 3D Optical Coherence Tomography in Macular diseases.

Published: 31-07-2008
Last updated: 07-05-2024

To improve imaging of sub-RPE structures with OCT.

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

Summary

ID

NL-OMON32046

Source
ToetsingOnline

Brief title
SDOCT & Macular diseases

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
macular diseases

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis Prof. Dr. H.J. Flieringa (SWOO).

Intervention

Keyword: Choroid, Imaging, Macular diseases, Optical coherence tomography

Outcome measures

Primary outcome

Correlation of clinical outcome parameters for structural data obtained with conventional imaging techniques and 1050 nm OCT.

Secondary outcome

- The attribution of structural characteristics to data obtained by 1050 nm OCT in accordance with data obtained by FAG/ICG imaging and histological data (ganglion cell, inner plexiform, inner nuclear, outer plexiform, outer nuclear, outer limiting membrane, inner and outer photoreceptor segment interface, retinal pigment epithelium and choroid).
- Comparison of structural data obtained with conventional imaging techniques and 1050 nm OCT.
- Correlation between repeated scans with 1050 nm OCT within one subject.

Study description

Background summary

In many retinal diseases, a significant loss of vision is caused either by choroidal neovascularization, or by pigment epithelium detachment. Because both processes occur underneath the RPE-layer, they are only partially visible by current OCT devices. This study aims to improve imaging of the sub-RPE layer.

Study objective

To improve imaging of sub-RPE structures with OCT.

Study design

Observational cross-sectional and longitudinal cohort-study.

Study burden and risks

Replacement of dye injection dependent diagnostics for macular diseases by a non-invasive imaging technique would be a major advantage for future patients, because dye related adverse effects could be eliminated.

Healthy volunteers are recruited for 2 visits. No side effects are anticipated for OCT measurements. If adverse effects of Fluorescein and ICG injections occur, they are expected to be mild. The risk of serious adverse effects is low. Total study time is (2X3=) 6 hours.
Patients with macular diseases do not benefit and receive no financial compensation. No side effects are anticipated for OCT measurements. Study related measurements always occur in combination with regular clinical visits. Duration of study related measurements is 20 minutes per visit (in an exceptional case maximally 60 minutes). Burden is considered to be low. Total study time is 2-6 hours (distributed over 4-8 visits in 1 year).
Patients due for autologous RPE/choroid graft do not benefit and receive no financial compensation. No side effects are anticipated for OCT measurements. Study related measurements will, in part, be scheduled together with regular clinical visits (7 visits); additionally, a number of extra study visits (4 visits) are planned. Duration of study related measurements is 4 hours, in total.
Patients due for enucleation do not benefit and receive no financial compensation. No side effects are anticipated for OCT measurements. Study related measurements occur in combination with a single regular clinical visit. Duration of study related measurements is 20-60 minutes. Burden is considered to be low.

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 volunteers:
- Age >= 18 years.
- Informed consent.;Patients with macular disease:
- Age >= 18 years.
- Informed consent.
- Letter reading skill (for ETDRS visual acuity determination).
- Definite macular disease, acute or chronic, of known etiology.
- Visual acuity of study eye >= 0.05 (Snellen).;Patients due for autologous RPE/choroid graft:
- Age >= 18 years.
- Informed consent.
- Letter reading skill (for ETDRS visual acuity determination).
- Exudative or atrophic ARMD.
- Visual acuity of study eye (within 1 week prior to 1st measurements) >= 0.05 (Snellen).;Patients requiring enucleation:
- Age >= 18 years.
- Informed consent (1050 nm OCT).
- No objection (histology).

Exclusion criteria

Healthy volunteers:
- Impossibility to visualize fundus due to corneal or lenticular opacities.
- Ocular disease, eg. retinal or ophthalmic disorder affecting macular area.;Patients with macular disease:

- Impossibility to visualize fundus due to corneal or lenticular opacities.
- Inability to obtain photographs to document CNV, e.g. due to allergy to fluorescein dye, ICG or lack of venous access.
- Ocular surgery scheduled within initial 12 months of treatment.
- Ocular surgery during last 3 months, except surgery for ARMD.;Patients due for autologous RPE/choroid graft:
- Impossibility to visualize fundus due to corneal or lenticular opacities.
- Inability to obtain photographs to document CNV, e.g. due to allergy to fluorescein dye, ICG or lack of venous access.
- Ocular surgery during last 3 months.;Patients requiring enucleation:
- Ocular turbidities preventing imaging.

Study design

Design

Study type:	Observational 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):	29-06-2009
Enrollment:	265
Type:	Actual

Ethics review

Approved WMO

Date:	31-07-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	02-06-2009
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	NL22480.078.08