Evaluation of intra- and transretinal blood flow in Retinal Angiomatous Proliferation detected with phase-resolved Optical Coherence Tomography before and after treatment

Published: 26-05-2014
Last updated: 20-04-2024

To visualize the different components of RAP lesions with high resolution Doppler OCT, and to evaluate the change in intra- and transretinal flow after treatment.

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-OMON45004

Source
ToetsingOnline

Brief title
RAP treatment evaluated with Doppler OCT

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
RAP

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: MD fonds;Postbus 2410;3500 GK Utrecht

Intervention

Keyword: Doppler OCT, intraretinal blood flow, RAP, transretinal blood flow

Outcome measures

Primary outcome

Structural changes and intra-/transretinal blood flow.

Secondary outcome

visual acuity

fundusphotography

FA/ICG

SD-OCT

Study description

Background summary

Retinal angiomatous proliferation (RAP) is a distinct form of neovascular age-related macular degeneration (ARMD) that responds poorly to anti-VEGF monotherapy. It is difficult to demonstrate RAP with conventional imaging (fluorescein or indocyanine angiography). Recently, we were able to demonstrate abnormal flow corresponding to intraretinal neovascularisation in treatment-naïve RAP patients with high resolution Doppler Optical Coherence Tomography (OCT) imaging.

Study objective

To visualize the different components of RAP lesions with high resolution Doppler OCT, and to evaluate the change in intra- and transretinal flow after treatment.

Study design

Prospective, observational cohort study.

Study burden and risks

Participants undergo treatment and follow-up through routine clinical care. With the exception of a single extra study-related visit, measurements will be combined with regular clinical visits. There are no anticipated major side effects associated with Doppler-OCT measurements. Burden is considered to be low. Study-related examinations will be performed at 0, 2, 4 and 18 weeks. These will take about two hours (0 and 18 wks) and one hour (2 and 4 wks) respectively. Total time: 6 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

Age * 60 years
Diagnosis of RAP based on fundus photography, FA and/or ICG
The study eye has not been treated for exudative ARMD for at least one year (i.e. no treatment with anti-VEGF, periocular steroids or laser in the study eye within the last year).
The specific RAP location has to be treatment-naïve for laser
Informed consent

Exclusion criteria

Ocular surgery within the last 3 months, with the exception of uncomplicated cataract surgery.
Participation in another ophthalmic trial requiring follow-up examinations or using an investigational drug within the last 12 weeks
Other active ocular diseases which irreversibly compromise or, during follow-up, are likely to compromise visual acuity or good visualization of the study eye including ocular surgery scheduled within 3 months after start of the study

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):	16-09-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	26-05-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-04-2017
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	NL48119.078.14