# Evaluation of intra- and transretinal blood flow in Retinal Angiomatous Proliferation detected with phaseresolved 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                  |
| Туре:                     | Actual              |

# **Ethics review**

| Approved WMO       |                                                                        |
|--------------------|------------------------------------------------------------------------|
| Date:              | 26-05-2014                                                             |
| Application type:  | First submission                                                       |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam<br>(Rotterdam) |
| Approved WMO       |                                                                        |
| Date:              | 19-04-2017                                                             |
| Application type:  | Amendment                                                              |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam<br>(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** CCMO

**ID** NL48119.078.14