# Adaptive optics in patients after rhegmatogenous retinal detachment

Published: 16-05-2024 Last updated: 07-12-2024

To demonstrate that cone density can be reliably and accurately measured after vitrectomy for RRD split fovea and for RRD macula-off.

**Ethical review** Approved WMO **Status** Recruiting

**Health condition type** Retina, choroid and vitreous haemorrhages and vascular disorders

**Study type** Observational non invasive

# **Summary**

#### ID

NL-OMON56746

Source

ToetsingOnline

**Brief title**AO-FIO in RRD

#### **Condition**

• Retina, choroid and vitreous haemorrhages and vascular disorders

#### **Synonym**

ablatio retinae, retinal detachment

#### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Oogziekenhuis Rotterdam

Source(s) of monetary or material Support: UitZicht; Stichting Wetenschappelijk

Onderzoek Oogziekenhuis (SWOO)

#### Intervention

**Keyword:** Adaptive Optics, Macular Edema, Vitrectomy

#### **Outcome measures**

#### **Primary outcome**

Cone density.

#### **Secondary outcome**

- Intercone spacing,
- Hexagonality,
- Presence of preoperative cystoid macula edema,
- Presence of preoperative proliferative vitreoretinopathy,
- Preoperative and postoperative best-corrected visual acuity of operated eye,
- Time between onset symptoms and time of surgery (in days),
- Integrity of ellipsoid zone and external limiting membrane within 500  $\mu m$  around the foveal center,
- Foveal detachment height,
- Usage of perfluorcarbon liquid.

# **Study description**

#### **Background summary**

Although OCT provides a detailed visualization of the retina in vivo, some complaints after vitrectomy for rhegmatogenous retinal detachment (RRD) remain unexplained. Adaptive optics flood illumination ophthalmoscopy (AO-FIO), an imaging technique visualizing individual cones, may provide more insight into damage and recovery of photoreceptor cells after RRD.

#### Study objective

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To demonstrate that cone density can be reliably and accurately measured after vitrectomy for RRD split fovea and for RRD macula-off.

#### Study design

Prospective, observational pilot.

#### Study burden and risks

Participation involves neither additional risk nor benefit. Extra study-related time is 3 hours in total.

### **Contacts**

#### **Public**

Oogziekenhuis Rotterdam

Schiedamse Vest 180 Rotterdam 3011 BH NL

#### **Scientific**

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# **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

#### Inclusion criteria

- Vitrectomy for RRD macula-off or for split fovea

#### **Exclusion criteria**

- Age < 18 years,
- No ability to attend follow-up visits,
- No ability to give informed consent.

Eye-related exclusion criteria for both eyes (post-RRD eye and fellow eye):

- Pupil size < 4 mm,
- Pre-existing maculopathy,
- Opacities in the cornea or lens,
- Irregular cornea,
- Instable tearfilm,
- Macular pucker stage 2 or more,
- Cystoid macular edema,
- Subretinal fluid,
- Macular fold,
- Myopia > 12 diopters,
- Hypermetropia > 6 diopters,
- Peroperative peeling of the inner limiting membrane,
- Silicone oil as a tamponade.

# 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: Basic science

#### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 20-09-2024

Enrollment: 20

Type: Actual

## Medical products/devices used

Generic name: RTX1 Adaptive Optics Retinal Camera

Registration: Yes - CE intended use

# **Ethics review**

Approved WMO

Date: 16-05-2024

Application type: First submission

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 NL85899.078.24