

# Visual function recovery in patients after rhegmatogenous retinal detachment without macular involvement

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To correlate structural modifications with visual function in patients after macula-on retinal detachment.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Retina, choroid and vitreous haemorrhages and vascular disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON47987

### Source

ToetsingOnline

### Brief title

Visual function after macula-on retinal detachment

### Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

### Synonym

retinal detachment

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam

**Source(s) of monetary or material Support:** Stichting voor ooglijders

## Intervention

**Keyword:** macula-on, retinal detachment, retinal structure, visual function

## Outcome measures

### Primary outcome

Macular function (as measured by microperimetry) and structural modifications (as measured by OCT and OCTA).

### Secondary outcome

Visual acuity

Contrast sensitivity

Color sensitivity

Metamorphopsia

Aniseikonia

## Study description

### Background summary

Vitreoretinal surgery for rhegmatogenous retinal detachment has a high reattachment rate and it is assumed that macular damage is limited as the macula is not involved. However, despite anatomically successful surgery for macula-on retinal detachment, patients can perceive unexplainable loss of vision<sup>1-4</sup>. Studies have shown structural modifications of the macula after macula-on retinal detachment, but these findings have not yet been correlated with visual function in long term<sup>5,6</sup>. We hypothesize that damage induced by the retinal detachment extends beyond the detached area, towards the fovea, which may result in structural modifications and visual function loss.

### Study objective

To correlate structural modifications with visual function in patients after macula-on retinal detachment.

## Study design

Prospective observational.

## Study burden and risks

Inconvenience of the additional tests is minimal. Risks associated with participation are negligible. Extra time for research assessments is estimated to be 8 hours.

## Contacts

### Public

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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

At least 18 years of age  
Primary rhegmatogenous retinal detachment without macular involvement: > 1250  
µm from fovea  
Healthy contralateral eye

## Exclusion criteria

Redetachment  
Tractie  
Proliferative retinal vascular disease

## Study design

### Design

**Study type:** Observational non invasive  
**Masking:** Open (masking not used)  
**Control:** Uncontrolled  
**Primary purpose:** Basic science

### Recruitment

NL  
**Recruitment status:** Pending  
**Start date (anticipated):** 01-03-2020  
**Enrollment:** 40  
**Type:** Anticipated

## Ethics review

Approved WMO  
**Date:** 21-01-2020  
**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	NL72120.078.19