

# Functional recovery related to duration of macular detachment in retinal detachment after surgery

Published: 04-10-2016

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To demonstrate that functional outcome is correlated with DMD and ocular blood flow.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Eye disorders NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON47105

### Source

ToetsingOnline

### Brief title

Recovery after macular detachment

### Condition

- Eye disorders NEC

### Synonym

macular detachment

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam

**Source(s) of monetary or material Support:** Stichting voor Ooglijders;Schipholweg 641;1175 KP Lijnden

## Intervention

**Keyword:** duration of macular detachment, macular detachment, retinal sensitivity, visual recovery

## Outcome measures

### Primary outcome

DMD, visual acuity.

### Secondary outcome

OCT, microperimetry, vision, contrast- and colour sensitivity.

## Study description

### Background summary

As the condition of the retinal photoreceptors depends on the ocular blood flow, it is supposed that the duration of a macular detachment (DMD) plays a crucial role in post-operative recovery.

### Study objective

To demonstrate that functional outcome is correlated with DMD and ocular blood flow.

### Study design

Prospective observational.

### Study burden and risks

Inconvenience is minimal and risks are considered to be negligible. Participants do not benefit. In total, study-related extra time is estimated to be 7 hours.

## Contacts

### Public

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**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

Informed consent.

Age \* 18 years.

Able and willing to attend follow-up visits until 12 months after surgery.

Able to provide an estimate of the onset ( $\pm$  1 day) of foveal detachment.

### Exclusion criteria

Macula-off > 14 days.

Error of time of onset of macular detachment > one day.

Ocular co-morbidity.

Re-detachment within one year.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 06-06-2017

Enrollment: 100

Type: Actual

## Ethics review

Approved WMO

Date: 04-10-2016

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 12-07-2017

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 23-05-2018

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	NL58405.078.16