

# Macula off rhegmatogenous retinal detachment and its functional recovery

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|--|---|---|
| <b>Submission date</b><br>16/01/2007   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>16/01/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>14/01/2021       | <b>Condition category</b><br>Eye Diseases         | <input type="checkbox"/> Individual participant data  |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
NL826, NTR839

# Study information

## Scientific Title

Macula off rhegmatogenous retinal detachment and its functional recovery

## Study objectives

Optimum timing of surgery for macula off rhegmatogenous retinal detachment can be determined in more detail by taking both duration and height of macular detachment into account.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approval received from the local ethics committee (Medisch Ethische Toetsingscommissie Universitair Medisch Centrum Groningen [METc UMCG]) on the 11th July 2006 (ref: 12551).

## Study design

Non-randomised prospective observational study

## Primary study design

Observational

## Secondary study design

Case-control study

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Rhegmatogenous retinal detachment

## Interventions

Vitreoretinal surgery according to current practice guidelines.

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

1. Visual acuity in relation to duration and height of macular detachment
2. Individual parameters relating to visual function, subjective contentness and morphology of the macula in relation to each other, duration and height of macular detachment

**Primary study group:**

Pre-operative and postoperative at one, three, six and 12 months.

**Secondary study group:**

Pre-operative and one year after the latest vitreoretinal surgery.

### **Secondary outcome measures**

1. Correlation between height macular detachment measured by ultrasonography and by optical coherence tomography
2. Relationship between subjective contentness in the primary and secondary study groups

### **Overall study start date**

01/02/2007

### **Completion date**

31/12/2011

## **Eligibility**

### **Key inclusion criteria**

**Primary study group:**

1. Rhegmatogenous retinal detachment with macula off during one day to six weeks
2. Retinal reattachment after one surgical intervention
3. No redetachment during the study period (one year)

**Secondary study group:**

Same as primary study group, but more than one vitreoretinal surgical procedure is needed to obtain retinal attachment.

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

200

### **Total final enrolment**

45

### **Key exclusion criteria**

1. Pre-existent ocular pathology in the study or fellow eye that significantly influences visual acuity
2. History of retinal detachment in the study or fellow eye

### **Date of first enrolment**

01/02/2007

**Date of final enrolment**

31/12/2011

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Center Groningen (UMCG)

Groningen

Netherlands

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## **Sponsor information**

**Organisation**

University Medical Center Groningen (UMCG) (The Netherlands)

**Sponsor details**

Department of Ophtalmology

P.O. Box 30001

Groningen

Netherlands

9700 RB

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.umcg.nl/azg/nl/english/azg/>

**ROR**

<https://ror.org/03cv38k47>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Dutch Foundation of Ophthalmologic Research (Stichting Nederlands Oogheelkundig Onderzoek) (The Netherlands)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 13/06/2014   | 14/01/2021 | Yes            | No              |