

Macula off rhegmatogenous retinal detachment and its functional recovery

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr D Croonen

Contact details
University Medical Center Groningen (UMCG)
Department of Ophthalmology
P.O. Box 30.001
Groningen
Netherlands
-
+31 (0)50 361 2510
d.croonen@ohk.umcg.nl

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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
-

Sponsor information

Organisation

University Medical Center Groningen (UMCG) (The Netherlands)

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

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?
Results article	results	13/06/2014	14/01/2021	Yes	No