ISRCTN76474643 https://doi.org/10.1186/ISRCTN76474643

Macula off rhegmatogenous retinal detachment and its functional recovery

Submission date	Recruitment status	[X] Prospectively registered
16/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/01/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/01/2021	Eye Diseases	

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

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