Macula off rhegmatogenous retinal detachment and its functional recovery.

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

Summary

ID

NL-OMON29789

Source
ToetsingOnline

Brief title
Rhegmatogenous retinal detachment, functional recovery

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
retinal detachment

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,nog aan te vragen fondsen. (SOON is reeds aangevraagd)

Intervention

Keyword: macula, OCT, retinal detachment, USG

Outcome measures

Primary outcome

1. Visual outcome in relation to time and height of detached macula preoperatively.

2a.Postoperative morphology of the macula in relation to visual outcome,

b. Postoperative morphology of the macula in relation to subjective satisfaction.

c. Visual outcome in relation to time and height of detached macula preoperatively

d. Visual outcome in relation to subjective satisfaction.

3. Surgical technique in relation to rapidity of postoperative visual recovery.

4a. Frequency of developing entoptic phenomena

b. Description of entoptic phenomena developing after retinal detachment surgery

Secondary outcome

1. correlation between height of detached macula measured with USG and OCT.

2. Visual outcome and subjective satisfaction differences between primary and secondary study group.

Study description

Background summary

A rhegmatogenous retinal detachment is a vision-threatening disease. If the macula is detached, chances are that visual recovery will not be complete. At this moment, it is hard to predict preoperatively what the postoperative visual outcome will be.
It is clear that timing of surgery influences the postoperative visual outcome; eyes that obtained surgery within1 to 9 days of detached macula will have a better visual outcome compared to eyes that did not obtain this surgery within this time frame. Within these 9 days no significant differences could be found. This is an unexpected result regarding experimental animal studies. These show progressive changes from 1 day up to 2 weeks after induction of a retinal detachment. A possible explanation between the discrepancy of experimental animal studies and the observational studies on humans may be that other visual outcome influencing factors also play a role. One explanation could be the amount of fluid in between the neurosensory retina and its retinal pigment epithelium (height of detached macula). This has been reported in several studies; unfortunately we could not find a study that combines above-mentioned factors.
Furthermore, after surgery patients mention sometimes spontaneously newly developed entoptic phenomena. Entoptic phenomenona are visual perceptions, produced or influenced by structures within the eye. Some of these phenomena are not understood.

Study objective

By observing several visual aspects in a large patient population we would like to obtain more information about the best time of surgical intervention (primary study group). 80% of the patients need only one surgical intervention to obtain an attached retina. The patient group with a detached retina after one surgical intervention will have an attached retina in 95% of the cases. We would like to observe the visual aspects of this group (secundairy study group) separately to get an impression of the additional damage by having a second retinal detachment and its surgical intervention.
Furthermore, we would like to get an impression of newly developed entoptic phenomena after retinal detachment surgery by interviewing the specific patients structurally. We hope to get a clue about the pathogeneses of the entoptic phenomenon mentioned after retinal detachment surgery.

Study design

Prospective observational study n = 200 eyes of rhegmatogenous retinal detachment patients, macula detached. (1 day to 6 weeks). Non-randomized (surgical technique will be decided by surgeon). Time of surgical intervention will be determined by the existing guidelines.

Study burden and risks

This study does not cause any risk factors for participating patients. The preoperative ophthalmic examination will take 65 minutes longer. Postoperatively the extra examination will be linked to regular appointments; on 1, 6 and 12 months postoperatively, which will make these visits 122 minutes longer. At 3 months postoperatively it will take 30 minutes longer.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-first rhegmatogenous retinal detachment
-macula detached
-no other pathology that can influence visual functioning

Exclusion criteria

-indication for immediate surgery
-visual functioning influencing pathology in the affected eye
-visual functioning influencing pathology non-affected eye
-history of retinal detachment, either eye

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL12551.042.06