

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

Published: 04-10-2016

Last updated: 15-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders NEC
Study type	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

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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