Adaptive optics in patients after rhegmatogenous retinal detachment

Published: 16-05-2024
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To demonstrate that cone density can be reliably and accurately measured after vitrectomy for RRD split fovea and for RRD macula-off.

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

Summary

ID

NL-OMON56746

Source
ToetsingOnline

Brief title
AO-FIO in RRD

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
ablatio retinae, retinal detachment

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: UitZicht;Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Keyword: Adaptive Optics, Macular Edema, Vitrectomy

Outcome measures

Primary outcome

Cone density.

Secondary outcome

- Intercone spacing,

- Hexagonality,

- Presence of preoperative cystoid macula edema,

- Presence of preoperative proliferative vitreoretinopathy,

- Preoperative and postoperative best-corrected visual acuity of operated eye,

- Time between onset symptoms and time of surgery (in days),

- Integrity of ellipsoid zone and external limiting membrane within 500 µm

around the foveal center,

- Foveal detachment height,

- Usage of perfluorcarbon liquid.

Study description

Background summary

Although OCT provides a detailed visualization of the retina in vivo, some complaints after vitrectomy for rhegmatogenous retinal detachment (RRD) remain unexplained. Adaptive optics flood illumination ophthalmoscopy (AO-FIO), an imaging technique visualizing individual cones, may provide more insight into damage and recovery of photoreceptor cells after RRD.

Study objective

To demonstrate that cone density can be reliably and accurately measured after vitrectomy for RRD split fovea and for RRD macula-off.

Study design

Prospective, observational pilot.

Study burden and risks

Participation involves neither additional risk nor benefit. Extra study-related time is 3 hours in total.

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

- Vitrectomy for RRD macula-off or for split fovea

Exclusion criteria

- Age < 18 years,
- No ability to attend follow-up visits,
- No ability to give informed consent.

Eye-related exclusion criteria for both eyes (post-RRD eye and fellow eye):
- Pupil size < 4 mm,
- Pre-existing maculopathy,
- Opacities in the cornea or lens,
- Irregular cornea,
- Instable tearfilm,
- Macular pucker stage 2 or more,
- Cystoid macular edema,
- Subretinal fluid,
- Macular fold,
- Myopia > 12 diopters,
- Hypermetropia > 6 diopters,
- Peroperative peeling of the inner limiting membrane,
- Silicone oil as a tamponade.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-09-2024
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	RTX1 Adaptive Optics Retinal Camera
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-05-2024
Application type:	First submission
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	NL85899.078.24