Does positioning influence the progression of retinal detachment?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29389

Source
Nationaal Trial Register

Health condition

Retinal detachment of the superior quadrants but with macula-on.

Sponsors and support

Primary sponsor: Het Oogziekenhuis Rotterdam
Postbus 70030
3000 LM Rotterdam
Source(s) of monetary or material Support: ZonMW, TopZorg
Postbus 93245
2509 AE Den Haag

Intervention

Outcome measures

Primary outcome

Unacceptable progression of RD (yes/no).

Distance between RD and fovea (µm).

Secondary outcome

Age (years)

Gender (M/F)

Lens status (phakic/pseudophakic)

Best corrected visual acuity (0.2 to 1.2)

Spherical equivalent refraction (Diopter)

Extent of RD on fundus drawing and # detached quadrants (1/2/3/4)

Posterior vitreous detachment (PVD; yes/no)

Clock hours of retinal tears (0 to 12)

Type of RD (bullous/flat)

Posturing instruction (supine on the back/supine on the temporal side)

Date (yy:mm:dd) and time (hh:mm) of OCT scans.
(OCT-0: baseline, OCT-1a & OCT-1b: start & end of 1st interruption of supine bedrest, etc.)

Type of interruption and duration.

Study description

Background summary

Rationale: Traditionally, patients with retinal detachment (RD) get posturing and positioning advise to prevent (or reduce) progression and, in particular, to prevent detachment of the fovea. Execution of such advise can be cumbersome and expensive. This study aims to acquire evidence which may corroborate such advise.

Objective: To study whether positioning influences RD progression.

Study design: Comparative, non-randomized, non-parallel, unmasked trial.

Study population: Patients with RD.

Intervention: Prolongation of the interruption of bedrest (cohorts 1-3: +0, +15 and +30 min).

Main study parameters/endpoints: Proportion of unacceptable progression, change of the distance between the border of RD and fovea.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: OCT does not involve additional risk, burden is low. Unacceptable progression may be detected sooner and surgery can be rescheduled. Possibly the risk of foveal involvement is somewhat increased in cohorts 2 & 3.

Study objective

Posturing advise for patients with retinal detachment can be more selective.

Study design

Admission

Start/end bedrest period 1

Start/end interruption 1

Start/end bedrest period 2

Start/end interruption 2

Etcetera

Surgery

Intervention

Interruption of supine bedrest by sitting upright for meals and other breaks, of progressive duration.

Contacts

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Eligibility criteria

Inclusion criteria

Age ≥ 18 years

Written informed consent

Sufficiently clear media to obtain an OCT scan

Sufficiently accurate OCT scan

RD with “fovea on”

RD involves the superotemporal quadrant

Central RD border is within the range of OCT imaging

Central RD border at ≥ 750 µm from the fovea

Exclusion criteria

None specified

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2015
Enrollment:	160
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	07-11-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40661
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4755
NTR-old	NTR4884

Register	ID
CCMO	NL50638.078.14
OMON	NL-OMON40661

Study results

Summary results

de Jong JH, Vigueras-Guillén JP, Simon TC, Timman R, Peto T, Vermeer KA, van Meurs JC. Preoperative Posturing of Patients with Macula-On Retinal Detachment Reduces Progression Toward the Fovea. Ophthalmology. 2017; 124(10): 1510-1522.

de Jong JH, de Koning K, den Ouden T, van Meurs JC, Vermeer KA. The Effect of Compliance With Preoperative Posturing Advice and Head Movements on the Progression of Macula-On Retinal Detachment. Transl Vis Sci Technol. 2019; 8(2):4.

Vroon J, de Jong JH, Aboulatta A, Eliasy A, van der Helm FCT, van Meurs JC,
Wong D, Elsheikh A. Numerical study of the effect of head and eye movement on progression of retinal detachment. Biomech Model Mechanobiol. 2018; 17(4): 975-983.

de Jong JH, Vigueras-Guillen JP, Wubbels RJ, Timman, R, Vermeer KA, van Meurs JC. The influence of prolongation of interruptions of preoperative posturing and other clinical factors on the progress of macula-on retinal detachment. Ophthalmol Retina. 2019; 3: 938-946.