

Macula off rhegmatogenous retinal detachment and its functional recovery.

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26742

Bron

NTR

Verkorte titel

Rhegmatogenous retinal detachment, functional recovery

Aandoening

Rhegmatogenous retinal detachment is an ocular condition in which the neuroretina has detached from the underlying retinal pigment epithelium. This may result in lasting problems with visual function, even if the retina becomes reattached through surgery. Problems may include reduced visual acuity, metamorphopsia, and reduced contrast acuity. These problems occur more frequently when the centre of the retina, the macula, is involved in the detachment.

Ondersteuning

Primaire sponsor: University Medical Centre Groningen, Department of Ophthalmology

Overige ondersteuning: Stichting Nederlands Oogheelkundig Onderzoek, application for further sponsoring is in progress.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Primary study group:

Pre-operative and postoperative at 1, 3, 6 and 12 months.

Secondary study group:

Pre-operative and 1 year after the latest vitreoretinal surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

A rhegmatogenous retinal detachment is a condition that can severely affect visual function, in particular when the macula is involved in the detachment. Previous studies evaluated whether duration of macular detachment or height of macular detachment influenced postoperative visual prognosis. Both factors - taken separately - are of importance, however when looking at duration of macular detachment no significant differences in visual recovery were observed between eyes with macular detachment of 1 to 9 days. The present study will evaluate whether differences in visual recovery can be related more strictly to duration of macular detachment when the data are corrected for height of macular detachment. This may result in a recommendation to change current practice with regard to patient scheduling in vitreoretinal surgery for rhegmatogenous retinal detachment.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

Vitreoretinal surgery according to current practice guidelines.

Contactpersonen

Publiek

University Medical Center Groningen (UMCG),
Department of Ophthalmology,
P.O. Box 30.001
D. Croonen
Groningen
The Netherlands
+31 (0)50 3612510

Wetenschappelijk

University Medical Center Groningen (UMCG),
Department of Ophthalmology,
P.O. Box 30.001
D. Croonen
Groningen
The Netherlands
+31 (0)50 3612510

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Primary study group:

1. Rhegmatogenous retinal detachment with macula off during 1 day to 6 weeks;
2. Retinal reattachment after one surgical intervention;
3. No redetachment during the study period (1 year).

Secondary study group:

same as primary study group, but more than one vitreoretinal surgical procedure is needed to obtain retinal attachment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2007
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	18-12-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

NTR-old

Ander register

ISRCTN

ID

NL826

NTR839

: N/A

ISRCTN76474643

Resultaten

Samenvatting resultaten

N/A