Epiretinal membrane vitreoretinal surgery assisted by a robotic system as compared to standard surgery

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22824

Bron
Nationaal Trial Register

Aandoening

Macula pucker
Epiretinal membrane
Epiretinaal membraaan
vision loss
visus daling

Ondersteuning

Primaire sponsor: Preceyes, Eindhoven, the Netherlands
Oogziekenhuis Rotterdam, Rotterdam, the Netherlands
Overige ondersteuning: Preceyes, Eindhoven, the Netherlands
Oogziekenhuis Rotterdam, Rotterdam, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Overall - degree of nerve fiber layer changes at 3 months post surgery in an OCT macular cube.
For individual surgical step: presence/absence of surgical trauma, retinal hemorrhage; response of the surgeon to a standard questionnaire post surgery

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The Preceyes Surgical System (PSS) is a high precision telemanipulated robot that assists surgeons at critical steps during vitreoretinal surgery. When needed during particular surgical steps, the surgeon can make use of the PSS, while at other time, the surgery is carried out manually. The surgical steps where PSS can be of assistance require a clinical evaluation.

Objective: Evaluated the performance of PSS assisted surgical steps as compared to manual surgery in at selected stages of macular pucker surgery.

Study design: Comparative study 2:1 randomization between robotic assistance and manual surgery.

Study population: Patients with an epiretinal membrane requiring surgery.

Intervention: Evaluated surgical steps will include: membrane staining, fluid-fluid exchange, initiation of a flap, peeling, air-fluid exchange, targeted illumination.

Main study parameters/endpoints: recording of the number of attempts/positioning, time to completion of the step and associated side effects.

Nature and extent of the burden and risks associated with participation, benefit and group

relatedness: The main inconvenience will be an increase in time as compared to standard surgery for the purpose of recording and documentation. Participants may benefit from the added precision and accuracy provided by the PSS.

Doel van het onderzoek

Robotic assisted surgery provides high precision and accurate movements that enhance a surgeon's surgical ability. In this phase IIa study, we will demonstrate that the Preceyes Surgical System is as safe in use as human surgery, that the surgical outcomes are equivalent or better.

Onderzoeksopzet

start and stop of each surgical step and overall for surgery.

The patients will be evaluated pre-operatively for vision, OCT, and at 3 months. If patients are able to return at a 6 month visit, the OCT contour will be also evaluated with regards to ganglion cell layer changes.

Onderzoeksproduct en/of interventie

Randomized patients 2:1 for robotic assistance vs standard surgery will undergo a vitreoretinal procedure to remove an epiretinal membrane. At various steps of the surgery, the step will be either carried out manually or with the assistance of a robotic system. The following steps will be studied: fluid staining, fluid-fluid exchange, epiretinal flap initiation, epiretinal membrane grap and peel, light pipe orientation and positioning, air-fluid gas exchange

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Epiretinal membrane requiring surgery and confirmed on Spectral OCT scans

BCVA (best corrected visual acuity) < 0.5

Age ¡Ý 18 years

Written informed consent obtained from the patient prior to inclusion in the study OR if patient cannot read, written informed consent has been provided by an impartial witness after written or verbal assent from the patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Presence of scleral ectasia in the area of trocar placement.

Prior surgery involving the sclera in the zone of trocar placement.

Prior surgery in the previous 3 months.

Myopia > 6 D.

Insufficient transparency of ocular media (e.g. lens opacity, vitreous haemorrhage) if this will not be removed at the time of surgery
Corneal decompensation or expected decompensation as a result of cataract surgery

Use of anticoagulants.

Patient unable to follow verbal instructions regarding positioning.

Patient unable to remain quiet and still for the duration of surgery.

Any patient that the surgeon feels is unfit to undergo surgery within this trial.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48774
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7376
NTR-old	NTR7584
CCMO	NL66979.078.18
OMON	NL-OMON48774

Resultaten