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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22824

Source
Nationaal Trial Register

Health condition

Macula pucker
Epiretinal membrane
Epiretinaal membraaan
vision loss
visus daling

Sponsors and support

Primary sponsor: Preceyes, Eindhoven, the Netherlands
Oogziekenhuis Rotterdam, Rotterdam, the Netherlands
Source(s) of monetary or material Support: Preceyes, Eindhoven, the Netherlands
Oogziekenhuis Rotterdam, Rotterdam, the Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Patient satisfaction based on a questionnaire. Similar evaluation on concerns by the operating room personnel. Time required for each surgical step and overall time involved in conducting surgery

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2018
Enrollment:	15
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48774
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results