# Comparison between Robotic Assisted versus Manual Tasks during Epiretinal Membrane Peeling Surgery

Published: 31-01-2019
Last updated: 25-03-2025

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

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Retina, choroid and vitreous haemorrhages and vascular disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON48774

**Source**
ToetsingOnline

**Brief title**
Robot versus manual epiretinal membrane peeling

### Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders
- Eye therapeutic procedures

**Synonym**
cellophane maculopathy, epiretinal membrane

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Preceyes BV
**Source(s) of monetary or material Support:** door OZR en Preceyes gezamenlijk ,Oogziekenhuis Rotterdam,Preceyes BV

## Intervention

**Keyword:** Comparison, Manual, Robot, Vitreoretinal

## Outcome measures

### Primary outcome

Comparison of the changes in the OCT nerve fiber layer thickness at 3 months and 6 months post surgery.

Count of the number of retinal surface hemorrhages at the end of the each procedure, and the number of retinal touches.

### Secondary outcome

Differences in a structured satisfaction questionnaire for the patient, surgeon and OR nurses following each surgery

Surgical time differences

Comparison of the safety profile and rate of complications between the two types of surgery

# Study description

### Background summary

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. A typical surgical procedure for vitreoretinal surgeons, where several of the common surgical steps are carried out is a macular pucker procedure.

### Study objective

Evaluated the performance of PSS assisted surgical steps as compared to manual

surgery in at selected stages of macular pucker surgery.

### Study design

Prospective comparative study 2:1 randomization between robotic assistance and manual surgery.

### Intervention

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

### Study burden and risks

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

## Contacts

**Public**
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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Epiretinal membrane requiring surgery and confirmed on Spectral OCT scans
BCVA < 0.5
Age * 18 years
Informed consent

## 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 |

| | |
|---|---|
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 09-05-2019 |
| Enrollment: | 15 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | PRECEYES Surgical System (robot) |
| Registration: | No |

## Ethics review

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|---|---|
| Approved WMO Date: | 31-01-2019 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 30-01-2020 |
| Application type: | Amendment |
| 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

ID: 22824

Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL66979.078.18 |

# Study results

Date completed: 26-11-2020

Results posted: 22-02-2022

Actual enrolment: 15

**First publication**
22-02-2022

**URL result**
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

**Internal documents**
File