

# EurEyeCase \* Clinical Trial

## Validation of the EurEyeCase\_CT system for robot-assisted retinal surgery

Published: 16-11-2017

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To obtain and evaluate OCT-probe recordings and to test the interaction between the OCT-probe and the robot.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Retina, choroid and vitreous haemorrhages and vascular disorders
<b>Study type</b>	Observational invasive

### Summary

#### ID

NL-OMON44615

#### Source

ToetsingOnline

#### Brief title

EurEyeCase\_CT

#### Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

#### Synonym

Vitreoretinal conditon

#### Research involving

Human

#### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam

**Source(s) of monetary or material Support:** EurEyeCase;The EU Framework Programme for Research and Innovation - Horizon 2020;Grant Agreement No 645331

## Intervention

**Keyword:** OCT probe, retinal surgery, robot

## Outcome measures

### Primary outcome

OCT recordings.

### Secondary outcome

Instrument movement and location.

## Study description

### Background summary

The EU funded project EurEyeCase H2020 aims to design instrumentation and control techniques to improve the clinical outcome of vitreo-retinal surgery. One result of this project is EurEyeCase\_CT, a combination of two modules, i.e. a robot system and a sensor system for intraocular distance measurement. The robot system allows both standard manual surgery and robot-assisted surgery. As it is essential to prevent unintended retinal damage by overshoots in instrument manipulation, an integrated fiber probe OCT system aims to measure the distance to the retina. In this study, the combined OCT-probe and robot system will be tested in patients who will undergo vitreoretinal surgery.

### Study objective

To obtain and evaluate OCT-probe recordings and to test the interaction between the OCT-probe and the robot.

### Study design

Proof of principle.

### Intervention

Insertion of the OCT probe in the eye and intraocular manipulation.

### Study burden and risks

Inconvenience is minimal and risks are moderate. Tests will take approximately 10 minutes. Participants do not benefit. In the future, functional outcome of treatment of vitreoretinal conditions may be improved.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Age \* 18 years.

Informed consent.

Vitreoretinal cases with BCVA < 0.5.

Surgery will be performed under general anaesthesia.

## Exclusion criteria

Prognosis of postoperative best corrected visual acuity (BCVA) in the operated eye \* 0.3.

Axial length > 28 mm.

Media opacity precluding safe retinal surgery.

BCVA of fellow eye < 0.5.

Use of anticoagulants.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 13-02-2018

Enrollment: 5

Type: Actual

### Medical products/devices used

Generic name: EurEyeCase\_CT system

Registration: No

## Ethics review

Approved WMO

Date: 16-11-2017

Application type: First submission

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

No registrations found.

### In other registers

Register	ID
CCMO	NL63238.078.17