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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	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

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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