Cataract surgery with FED

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28829

Source
NTR

Brief title
NA

Health condition

- Fuchs' endothelial dystrophy
- Cataract

Sponsors and support

Primary sponsor: The Rotterdam Eye Hospital
Source(s) of monetary or material Support: ZonMW, TopZorg
Postbus 93245
2509 AE Den Haa

Intervention

Outcome measures

Primary outcome

At one month: the number of patients (not) requiring posterior lamellar keratoplasty (PLK); this in relation to the preoperatively measured corneal backscatter (on in vivo confocal microscope).

Secondary outcome

- OCT grayscale of the corneal stroma.

- Best corrected visual acuity (BCVA; ETDRS).

- Pachymetry (Tomey).

- Contrast sensitivity (CS; Pelli-Robson).

- Straylight (C-Quant).

- VFQ-25 questionnaire.

Study description

Background summary

Rationale: Fuchs' endothelial dystrophy (FED) is associated with a reduction of the corneal endothelial cell density (ECD). As cataract surgery may enhance cell loss, and lead to corneal edema and reduced vision, it may become necessary to restore vision by posterior lamellar keratoplasty (PLK). With advanced FED, the ECD itself happens to be an unreliable parameter. Instead, we will evaluate backscatter on in vivo confocal microscopy (IVCM) as a possible decisive preoperative measure for the clinical choice between phaco-emulsification or triple procedure in eyes with FED and cataract.

Objective: To study IVCM backscatter measurements as a usefull measurement to decide between surgical indications.

Study design: Prospective observational trial.

Study population: Patients with advanced FED indicated for cataract surgery.

Intervention: None.

Main study parameters/endpoints: Preoperative corneal backscatter; postoperative number of patients requiring PLK (y/n).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Particpants do not benefit. Assessments will be scheduled at the time of regular visits. Additional measurements include two IVCM assessments which involve contact with the cornea. Extra measurements will take about two times one hour.

Study objective

In vivo confocal microscopy (IVCM) backscatter measurements is a usefull measurement to decide whether patients with FED and cataract should undergo either a phaco or a triple procedure.

Study design

Preop, 1 month.

Intervention

None.

Contacts

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Eligibility criteria

Inclusion criteria

- Age ≥ 18 years.

- Informed consent.

- FED stage ≥ 2.

- Cataract requiring surgery.

- Visual acuity (VA) < 0.5.

Exclusion criteria

- Indication for triple procedure.

- History of other ocular disorders affecting VA.

- History of intra-ocular, corneal or refractive surgery.

- Severe nystagmus.

- Corneal opacity in the pre-pupillary region not related to FED.

- Corneal neovascularization > 1 quadrant.

- Amblyopia.

- Expected VA after surgery < 0.6.

- Fellow eye already included in this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-06-2015
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-06-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42593
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5067
NTR-old	NTR5198
CCMO	NL52626.078.15
OMON	NL-OMON42593

Study results

Summary results

Engel A, Wubbels R, van Goor T, Remeijer L, Geerards AJ, Vigueras-Guillén JP, van Rooij J. Pre-operative measurements to decide whether to combine a cataract surgery and a keratoplasty in eyes with Fuchs' endothelial dystrophy, Acta Ophthalmol. 97 (Suppl. S262), 5-6, 2019. [Abstract]