Clinical decision making in patients with cataract and Fuchs* endothelial dystrophy (FED): validation of in vivo confocal microscopy backscatter and OCT as a predictive measurements to decide to perform a phaco- or triple procedure.

Published: 23-04-2015
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To study IVCM backscatter measurements as a usefull measurement to decide between surgical indications.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42593

Source
ToetsingOnline

Brief title
Clinical decisions in patients with cataract and FED

Condition

- Eye disorders NEC

Synonym
Cataract and FED

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Backscatter on confocal microscope, Cataract, FED

Outcome measures

Primary outcome

Preoperative corneal backscatter; postoperative

number of patients requiring PLK (y/n).

Secondary outcome

Preoperative:

- LOCS III classification of cataract.

Preoperative and one month postoperative:

- 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.

Perioperative:

- Phaco time and energy.

Study description

Background summary

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.

Study objective

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

Study design

Prospective observational trial.

Study burden and risks

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.

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.
- FED stage = 2.
- Cataract requiring surgery.
- Visual acuity (VA) < 0.7.

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
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	23-04-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2015
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: 28829
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52626.078.15
OMON	NL-OMON28829