Cataract surgery with Fuchs* endothelial dystrophy.

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Evaluation of pre-operative parameters in order to ascertain the need for a keratoplasty after cataract surgery has been performed in eyes with Fuchs* endothelial dystrophy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular structural change, deposit and degeneration NEC
Study type	Observational non invasive

Summary

ID

NL-OMON31161

Source
ToetsingOnline

Brief title
Cataract surgery with Fuchs

Condition

- Ocular structural change, deposit and degeneration NEC

Synonym
Fuchs endothelial dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis - Prof Dr H J Flieringa

Intervention

Keyword: Cataract surgery, Fuchs endothelial dystrophy, Keratoplasty, Risk factors

Outcome measures

Primary outcome

Indication for keratoplasty within 1 year following cataract surgery, VA <= 0.4.

Time to decision for keratoplasty within 1 year following cataract surgery.

Secondary outcome

BCVA (ETDRS chart) after 2 and 12 months following cataract surgery.

Evaluation of two different techniques for pachymetry.

Study description

Background summary

Due to a limited amount of available data, no generally accepted criteria have been defined for the ophthalmologist to decide how to treat a patient suffering from Fuchs* endothelial dystrophy when cataract surgery becomes necessary. This study aims to systematically collect data which, together with available data from other studies, will asses the risk and risk factors for corneal decompensation after cataract extraction in Fuchs* endothelial dystrophy.

Study objective

Evaluation of pre-operative parameters in order to ascertain the need for a keratoplasty after cataract surgery has been performed in eyes with Fuchs* endothelial dystrophy.

Study design

This is a prospective observational non-intervention study.

Study burden and risks

Fuchs patients due for cataract surgery are standardly scheduled for one pre-op and three post-op visits. Study-related measurements will be performed during

the pre-op visit and the visits at 2 months and 1 year post-op. These will take approximately 40 minutes extra time per visit. Participants of this study do not benefit from the results of this study. Risks are negligible.

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

- Fuchs* endothelial dystrophy
- Indication for cataract surgery
- > 18 years of age
- BCVA < 0.5

Exclusion criteria

- Indication for Triple Procedure (e.g. far advanced grade III, by which cataract surgery alone would not be possible due to poor visualisation)
- Retinal disorders (e.g. age-related macular degeneration)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-01-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2007
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	NL17005.078.07