Patients with Fuchs endothelial dystrophy: evaluation of preoperative quality of vision and postoperative follow-up after posterior lamellar keratoplasty

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To evaluate long term results of DSEK and to compare pre- and postoperative quality of vision in patients with Fuchs' endothelial dystrophy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31840

Source
ToetsingOnline

Brief title
Fuchs dystrophy: pre- and postoperative evaluation after PLK

Condition

- Vision disorders

Synonym
corneal dystrophy, partial corneal transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Instituut voor Neurowetenschappen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fuchs endothelial dystrophy, Posterior lamellar keratoplasty, Postoperative follow-up, Quality of vision

Outcome measures

Primary outcome

1) Evaluation of the long term clinical results of DSEK: what is the

improvement in quality of vision as compared to the pre-operative situation?

2) Correlation of the endothelial cell count, keratometry and corneal and

posterior transplant thickness with the improvement in quality of vision.

Secondary outcome

not applicable

Study description

Background summary

Descemet-stripping endothelial keratoplasty (DSEK) is a relatively new surgical treatment for Fuchs' endothelial dystrophy. Fuchs* endothelial dystrophy is a common inheritable disorder leading to a slow loss of corneal endothelial cells. As these cells can't divide, the lost cells will not be replaced.
Patients with advanced Fuchs' endothelial dystrophy often complain of deterioration of visual acuity, glare and haloes. They can also suffer from irritation and even pain. There are not many options for medical treatment. Till a few years ago, corneal transplantation was the only available therapeutic option for this group of patients.
DSEK was first described in 1998 and is performed in the AMC since 2001. Currently, it is a universally accepted surgical technique. The main difference with penetrating keratoplasty is that only the diseased posterior lamella of the cornea is replaced (consisting of the posterior stroma, Descemet's membrane and the endothelium). Major advantages of replacing only the posterior part of

the cornea are: less intraoperative complications, no suture related problems (as no sutures are used), no irregular astigmatism, a less vulnerable wound and less risk of rejection. However, long term results of DSEK are not known yet.

Study objective

To evaluate long term results of DSEK and to compare pre- and postoperative quality of vision in patients with Fuchs' endothelial dystrophy.

Study design

It is an observational cohort study.
Pre- and postoperatively quality of vision will be evaluated by:
- documentation of subjective complaints with a validated questionnaire, the VFQ-25
- measurement of best corrected visual acuity
- straylight measurement
- orbscan measurement to determine thickness and keratometry of the cornea
- endothelial cell count
- anterior segment OCT measurement

All examinations are non-invasive and non-contact and without any risk for the patients.

Study burden and risks

The patients will make one to two study visit to the Department of Ophthalmology, lasting between 2 and 3 hours. The measurements will pose no extra risk for the patients.

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

1) Fuchs' endothelial dystrophy; either unoperated patients or after PLK
2) Able and willing to participate in the study and to understand and sign the informed consent form

Exclusion criteria

1) Patients with Fuchs' endothelial dystrophy and other opthalmological conditions which can influence quality of vision
2) Not able or unwilling to participate in the study or to understand and sign the informed consent form

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL23685.018.08