Endothelial transplants of smaller size and/or lower cell density

Published: 09-09-2015
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To determine whether corneal clearance is obtained with endothelial transplants of smaller size and/or lower endothelial cell counts.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Eye disorders
Study type	Interventional

Summary

ID

NL-OMON47809

Source
ToetsingOnline

Brief title
Transplant size and/or cell density

Condition

- Eye disorders
- Eye therapeutic procedures

Synonym
Fuchs endothelial dystrophy / corneal disease

Research involving
Human

Sponsors and support

Primary sponsor: Netherlands Institute for Innovative Ocular Surgery (NIIOS)
Source(s) of monetary or material Support: gefinancierd vanuit NIIOS.

Intervention

Keyword: Descemet, DMEK, Endothelium

Outcome measures

Primary outcome

- Visual acuity, measured by the optometrist using a Snellen chart (standard procedure, also used for DMEK)

Secondary outcome

- Endothelial cell density, as assessed by specular microscopy.

- Proportion of detachment, as assessed by OCT.

- Number of 'rebubblings', re-transplants (includes re-surgery with a regular-sized transplant), and complications.

- Pachymetry of the cornea, measured using a Pentacam apparatus and an Anterior Segment Optical Coherence Tomography apparatus (OCT).

Study description

Background summary

Descemet membrane endothelial keratoplasty (DMEK), i.e. the transplantation of Descemet membrane in its anatomical position, is currently the most advanced corneal transplant technique in the treatment of Fuchs endothelial dystrophy (FED). Recently, we requested and received METC approval for Descemet membrane endothelial transferral (DMET), in which the donor Descemet membrane is positioned in the anterior chamber of the eye (i.e. not in its anatomical position), because clinical observation suggested that the host endothelium significantly contributes to postoperative corneal clearance. Although tissue restoration may be 'more physiological', compared to DMEK visual recovery after DMET is relatively slow. We therefore investigated the possibility of hybrid techniques in which a transplant of different size and/or with a lower cell density is implanted, using routine DMEK surgical techniques, but with the aim to obtain corneal clearance through host endothelial outgrow as in DMET. An additional advantage of such a hybrid technique may be that the donor tissue

availability may significantly increase, because more than one transplant can be obtained from a single donor cornea.

Study objective

To determine whether corneal clearance is obtained with endothelial transplants of smaller size and/or lower endothelial cell counts.

Study design

Cohort study.

50 eyes suffering from Fuchs endothelial dystrophy will be included.

All eyes will undergo endothelial keratoplasty with routine DMEK surgical techniques, but with a transplants that differ in size and/or endothelial cell counts, as compared to regular DMEK

Before, and at 1 day, 1 week, 1 month, 6 months, 9 months, 12 months, all eyes will be evaluated using slitlamp biomicroscopy, Pentacam imaging, specular microscopy, optical coherence tomography (OCT), and confocal microscopy. Best corrected visual acuity and complications will be documented at all examinations.

In the event of primary or secondary transplant failure, routine DMEK will serve as a surgical back-up procedure.

Intervention

All patients receive one surgery to implant the adapted transplant. Sometimes a 'rebubbling' might be necessary, as with regular DMEK. If the results are suboptimal after 6 months, an additional surgery (standard DMEK) will be performed.

Study burden and risks

The extend of burden is comparable to a standard DMEK if everything is going according to plan (i.e., one surgery, and non-invasive check-ups post-surgery). If the transplant fails, one additional eye surgery will be needed.

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 a corneal transplant

Exclusion criteria

- Concomitant ocular disease or a contraindication for this type of surgery

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-01-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	09-09-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	08-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL52812.098.15