Descemetorhexis only* for treatment of Fuchs endothelial dystrophy

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To determine whether corneal clearance of FED eyes within the first 6 months after the procedure is obtained by using *descemetorhexis only* after removal of DM, guttae and/or the affected endothelium.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Eye disorders
Study type	Interventional

Summary

ID

NL-OMON45640

Source
ToetsingOnline

Brief title
Descemetorhexis only for FED

Condition

- Eye disorders
- Eye therapeutic procedures

Synonym
Fuchs endothelial dystrophy / corneal disease

Research involving
Human

Sponsors and support

Primary sponsor: Melles Hoornvlieskliniek Rotterdam (MHR)
Source(s) of monetary or material Support: Gefinancierd vanuit Melles Hoornvlieskliniek Rotterdam.

Intervention

Keyword: Descemet Membrane, 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 and confocal microscopy,

- number of complications,

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

- corneal clarity; if the cornea fails to clear within the first 6 months after surgery, the patient will receive a re-operation (DMEK).

- intraocular level of inflammation as measured with laser flare photometry

Study description

Background summary

Fuchs endothelial dystrophy (FED) is a disorder that affects primarily the endothelium and Descemet membrane (DM). Currently, the most advanced technique to treat FED is Descemet membrane endothelial keratoplasty (DMEK), where just the affected tissue is replaced with healthy donor tissue in its anatomical position. Recently, we requested and received METC approval for Descemet membrane endothelial transferal (DMET) (CCMO: NL42594.098.12), in which the donor Descemet membrane (DM) is positioned in the anterior chamber of the eye, because clinical observation suggested that the host endothelium significantly contributes to postoperative corneal clearance even when not in its anatomical position. Although tissue restoration may be *more physiological*, visual

recovery after DMET is relatively slow compared to DMEK. Furthermore, it was recently shown that certain FED corneas can clear with *descemetorhexis only*. This technique includes removal of the diseased recipient DM and endothelial cells without replacement by donor tissue. Over time, cells migrate from the periphery and repopulate the denuded area, forming a new cellular layer. We therefore want to investigate the possibility of removing only the affected endothelium and guttae of central FED corneas, with the aim to obtain corneal clearance through host endothelial outgrow as in DMET. The advantage is that donor tissue is not needed and associated complications (e.g. allograft rejection) are avoided. *Descemetorhexis only* can be done by tissue removal through YAG laser treatment and/or manual surgery.

Study objective

To determine whether corneal clearance of FED eyes within the first 6 months after the procedure is obtained by using *descemetorhexis only* after removal of DM, guttae and/or the affected endothelium.

Study design

Cohort study.

20 patients with an ocular disorder owing to Fuchs endothelial dystrophy will be included.

All eyes will undergo selective removal of guttae and endothelium with surgery and/or YAG laser treatment.

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

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

Intervention

The intervention includes removal of the diseased DM, endothelial cells and guttae from the central part of the cornea by manual surgery and/or low energy YAG laser. This area will be filled in by endothelial wound healing through cell migration.

Study burden and risks

- A lesser burden to the patient compared to standard DMEK because post-treatment complications associated with donor tissue should be eliminated.
- When YAG treatment may even be less invasive than manual surgery.
- In case cornea does not clear in six months, the patient will receive routine transplant (DMEK).

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
- Age * 18 years
- Agree to return for 1 day, 1 week, 1 month, 3 months 6 months, 9 months, and 12 months post-procedure follow-up visits

Exclusion criteria

- Concomitant ocular disease and/or a contraindication for this type of treatment (e.g. inflammation of the eye, uveitis etc.)
- (Functional) oculus ultimus
- Severe diabetes
- Unable to sit on a chair in front of the laser for 30 minutes
- Unable to clearly understand the language used in the clinic (Dutch)
- Inability to give informed consent for any reason
- Pregnant or nursing

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-05-2017
Application type:	First submission
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	NL60612.098.17