Pilot-study; Investigation on the application of a new surgical technique (DMET) for treatment of Fuchs endothelial dystrophy

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To simplify the operational technique for the eye surgeon. To minimize the risk of complications which occur occasionally with the standard technique, such as glaucoma and cataract. In addition, the surgery is less burdensome to the patient since...

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

Summary

ID

NL-OMON44087

Source
ToetsingOnline

Brief title
DMET pilot-study

Condition

- Eye disorders
- Eye therapeutic procedures

Synonym
Fuchs endothelial dystrophy / corneal weakness

Research involving
Human

Sponsors and support

Primary sponsor: 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)

- Pachymetry of the cornea --> measured using a pentacam apparatus and an Anterior Segment Optical Coherence Tomography apparatus (OCT) (standard procedures)

Secondary outcome

- Density of endothelial cells postoperative --> measured using a non-contact specular microscope (standard procedure)

Study description

Background summary

As described earlier in one of our papers (Recipient endothelium may relate to corneal clearance in Descemet membrane endothelial transfer. M. Dirisamer et al. 2012), 12 patients suffering from Fuchs endothelial dystrophy or bullous keratopathy are treated with a DMEK (Descemet membrane endothelial keratoplasty) which is a standard operation technique at our clinic. With these 12 patients it was not possible to unroll the transplant and place it on the recipient stroma, due to complications during the operation. A small part of the donor tissue did attach to the recipient stroma, the rest was floating in the anterior chamber as a flat detachment. Thus, the majority of the stroma remained without new endothelium and Descemet membrane. Since endothelial cells normaly function as small pumps which pump the excess of fluid out of the

cornea, expectations were that the cornea would be swollen and turbid. This appeared true for patients suffering from Bullous keratopaty (5 patients). Remarkably, for patients that suffered from Fuchs endothelial dystrophy (7 patients) a thinner and more transparent cornea was observed. In two cases the visual acuity increased as well (from 0.4 preoperative to 1.0 six months postoperative and from 0.15 preoperative to 0.7 six months postoperative). In the remaining 5 patients the visual acuity did not improve, but this was caused by the fact that the transplanted tissue was in front of the visual axis.

Study objective

To simplify the operational technique for the eye surgeon. To minimize the risk of complications which occur occasionally with the standard technique, such as glaucoma and cataract. In addition, the surgery is less burdensome to the patient since the surgery is much shorter than the DMEK surgery and the patient does not have to look towards the ceiling for 2 to 3 days after the surgery in order to achieve adherence of the graft.

Study design

Patients suffering from Fuchs endothelial dystrophy (but still have enough cells left in the peripheral part of the cornea) and should be operated on will be informed on the standard (DMEK) technique as well as on the new experimental (DMET) technique. When the patient chooses to cooperate in our pilot-study the operation will proceed according to the protocol of the old DMEK technique, only after insertion of the graft, the edge of the graft will be fixed in the incision and positioned in a way that the graft is not interfering with the visual axis. Postoperative check ups will take place after 1 day, 1 week, 1, 3 and 6 months. If the cornea does not clear within 6 months, the patient will undergo a reoperation (DMEK).

Intervention

All patients will undergo 1 DMET operation. If the cornea fails to clear within 6 months, the patient will undergo a reoperation (DMEK).

Study burden and risks

Postoperative check ups will take place after 1 day, 1 week, 1, 3 and 6 months. Risks are expected to be low. The operational procedure is less complicated and less burdensome to the patient since the surgery is much shorter than (all) other lamellar keratoplasty procedures and also has a lower complication risc. Recovery of the visual acuity may take somewhat longer than with the DMEK procedure.

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

Patients suffering from Fuchs endothelial dystrophy with no cells left in the center of the cornea, but still possessing cells at the periphery of the cornea.

Exclusion criteria

When no endothelial cells are present in the peripheral part of the cornea

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2015
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	26-04-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-12-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-09-2016
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	NL42594.098.13