A Randomized, Comparative Trial of Two Posterior Lamellar Keratoplasty Techniques.
Ultrathin Descemet Stripping Automated Endothelial Keratoplasty (UTDSAEK) versus Descemet Membrane Endothelial Keratoplasty (DMEK).

Published: 11-12-2014
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To demonstrate that DMEK is superior to DSAEK with respect to VA.

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

Summary

ID

NL-OMON41108

Source
ToetsingOnline

Brief title
UTDSAEK & DMEK

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: ZonMW

Intervention

Keyword: Donor graft preparation, Fuchs' endothelial dystrophy, Lamellar keratoplasty

Outcome measures

Primary outcome

Number of letters gained at 12 months.

Secondary outcome

LogMAR Best Corrected Visual Acuity (BCVA) at 1, 3, 6, 12 months.

Rate of vision recovery.

Contrast sensitivity and stray light at 1, 3, 6 and 12 months.

RMS (root mean square) of Zernike polynomials of total high order aberrations.

Quality of vision questionnaire at 1, 3, 6 and 12 months.

Endothelial cell density of the grafts at 6 and 12 months.

Number of graft detachments.

Number of graft failures.

OT time and costs.

Study description

Background summary

With advanced stages of Fuchs* endothelial dystrophy (FED), keratoplasty is the only manner to restore vision. Although lamellar techniques, nowadays, are generally prefered, there is an ongoing debate whether Ultrathin Descemet

Stripping Automated Endothelial Keratoplasty (UTDSAEK) or Descemet Membrane Endothelial Keratoplasty (DMEK) should be the procedure of choice in FED.

Study objective

To demonstrate that DMEK is superior to DSAEK with respect to VA.

Study design

Randomised, comparative.

Intervention

UTDSAEK or DMEK.

Study burden and risks

The outcome of DMEK may be more favorable but the risk of detachment is higher. Assessments for this study are non-invasive and inconvenience is negligible, extra time required is approximately 1 hour per visit (5X).

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

Age * 18 years.
Informed consent.
Fuchs* endothelial dystrophy.
VA < 0.6 (Snellen).

Exclusion criteria

Unable to attend the FU visits.
Previous keratoplasty in the eye to be included.
Severe progressive glaucoma (stable glaucoma on topical therapy is excepted).
History of retinal surgery, glaucoma surgery or age related macular disease.
Amblyopia.
Expected postoperative VA < 0.6.
Corneal neovascularisation > 1 quadrant.
Indication for typed graft.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2014
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	NL50956.078.14