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

Published: 30-11-2020
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To demonstrate that DMEK is superior to DSAEK with respect to visual acuity and quality of vision.

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

Summary

ID

NL-OMON49409

Source
ToetsingOnline

Brief title
UTDSAEK versus DMEK

Condition

- Eye disorders NEC

Synonym
Fuchs endothelial dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting ooglijders

Intervention

Keyword: Descemet Membrane Endothelial Keratoplasty (DMEK), Ultrathin Descemet Stripping Automated Endothelial Keratoplasty (UTDSAEK), Visual function

Outcome measures

Primary outcome

Number of letters gained at 12 months.

Secondary outcome

LogMAR Best Corrected Visual Acuity (BCVA) at baseline and at 1, 3, 6, 12

months.

Rate of LogMAR BCVA recovery.

Number of graft detachments / rebubling procedures.

Number of graft failures.

Endothelial cell density at 1 and 12 months.

Contrast sensitivity at baseline and 12 months.

RMS Zernike polynomials.

Quality of vision at baseline and at 12 months.

OT time.

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 visual acuity and quality of vision.

Study design

Randomised, comparative.

Intervention

UTDSAEK or DMEK.

Study burden and risks

The outcome of DMEK may be more favourable but the technique is challenging and the risk of graft detachment may be higher. Assessments for this study are non-invasive and inconvenience is negligible, extra time required is maximally 1 hour per visit (5X; total time 4 h).

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).
Pseudophakia.

Exclusion criteria

Previous keratoplasty in the eye to be included.
Severe progressive glaucoma.
History of retinal surgery, glaucoma surgery or age related macular disease.
Amblyopia.
Expected postoperative VA < 0.6.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-05-2021
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-03-2022
Application type:	Amendment
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	NL73183.078.20
Other	NL8938