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

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24220

Source
Nationaal Trial Register

Health condition

Fuchs'endothelial dysthrophy
and indication for keratoplasty

Sponsors and support

Primary sponsor: The Rotterdam Eye Hospital
PO Box 70030
3000 LM Rotterdam
010- 401 77 77

Source(s) of monetary or material Support: ZonMW

Intervention

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 LogMAR BCVA recovery in both groups (RMANOVA).
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

Rationale: 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.
Objective: To demonstrate that DMEK is superior to DSAEK with respect to VA.
Study design: Randomised, comparative.
Study population: Patients with FED indicated for keratoplasty.
Intervention: UTDSAEK or DMEK.
Main study parameters/endpoints: Number of letters gained at 12 months.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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).

Study objective

DMEK is superior to DSAEK in terms of (rate of) VA rehabilitation.

Study design

baseline, 1,3,6,12 month

Intervention

Ultrathin Descemet Stripping Automated Endothelial Keratoplasty (UTDSAEK)
Descemet Stripping Automated Endothelial Keratoplasty (DMAEK)

Contacts

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Eligibility criteria

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:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2015
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-12-2014
Application type:	First submission

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
NTR-new	NL4805
NTR-old	NTR4945
Other	NL50956.078.14 : OZR 2014-20

Study results

Summary results
Not Applicable