Corneal transplantation by ultra-thin DSAEK: thinner grafts, better vision?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25888

Source
Nationaal Trial Register

Brief title
Ultra-thin DSAEK study

Health condition

Irreversible corneal endothelial failure.

Sponsors and support

Primary sponsor: Maastricht University Medical Center / University Eye Clinic Maastricht
Source(s) of monetary or material Support: ZonMw; SNOO; Dr. F.P. Fischer-Stichting; LSBS

Intervention

Outcome measures

Primary outcome

Primary outcome measure is best corrected visual acuity (BCVA) 12 months postoperatively.

Secondary outcome

Secondary outcome measures are contrast acuity, refractive and topographic astigmatism, quality of vision (measured by contrast sensitivity measurements and stray light measurements), endothelial cell loss, incidence of graft rejection, primary graft failure, cornea donor loss due to preparation, and generic and vision-related quality of life (measured by validated questionnaires). Furthermore, adverse events, including complications, will be reported for each patient.

Study description

Background summary

Objective(s) / research question(s):

Corneal transplantation improves vision and quality of life in patients with corneal disease. Currently, the predominant technique for patients with corneal endothelial disease is Descemet Stripping Automated Endothelial Keratoplasty (DSAEK), in which only the posterior side of the cornea is transplanted. However, visual rehabilitation after DSAEK may be variable. In ultra-thin DSAEK, the donor tissue is thinner, which results in better visual outcomes and, consequently, a better quality of life. The objective of this project is to assess the effects and costs of ultra-thin DSAEK vs. standard DSAEK in order to determine whether the new technique is effective and cost-effective over the standard technique.

Study design:

Multicenter randomized clinical trial.

Study population(s) / datasets:

The study population will consist of 66 patients with irreversible corneal endothelial failure due to Fuchs’ endothelial dystrophy who need corneal transplantation.

Intervention:

The intervention consists of the performance of standard DSAEK (grafts of approximately 200 microns) or ultra-thin DSAEK (grafts of approximately 100 microns).

Outcome measures:

Primary outcome measure is best corrected visual acuity 12 months postoperatively. Secondary outcome measures are contrast acuity, astigmatism, quality of vision, endothelial cell loss, incidence of graft rejection, primary graft failure, cornea donor loss due to preparation, and generic and vision-related quality of life.

Sample size calculation / data analysis:

Sample size calculation for the outcome measure best corrected visual acuity 12 months postoperatively is based on an expected mean

difference in BSCVA of 0.15 LogMAR between DSAEK and UT-DSAEK with a standard deviation of 0.2

LogMAR. Assuming alpha of 0.05 and power of 80% yields a sample size of 58 patients. Accounting for

an anticipated dropout rate of 15%, 33 patients need to be included in both the experimental and the control group. Data analysis will be performed using point estimates and 95% confidence intervals.

Economic evaluation: An economic evaluation will be performed from a societal and a health care perspective with a time horizon of 12 months. Incremental cost-effectiveness ratios will be calculated. Standard sensitivity analyses and bootstrap analysis will be performed to investigate the uncertainty surrounding the cost-effectiveness ratios.

Time schedule:

Patients will be included during the first 9 months of the study. After a follow-up of 12 months, data analysis will be performed in the final 3 months.

Study objective

In patients with irreversible corneal endothelial failure, corneal transplantation is the only effective treatment. Currently, the predominant transplantation technique for patients with corneal endothelial disease is Descemet Stripping Automated Endothelial Keratoplasty (DSAEK) where a donor lamellar disk consisting of posterior stroma, Descemet's membrane and endothelium is dissected with the use of a microkeratome. However, visual rehabilitation after DSAEK may be variable. Better visual outcomes are achieved by using Descemet Membrane Endothelial Keratoplasty (DMEK) in which a very thin disk of isolated donor Descemet's membrane with endothelium is transplanted. Although DMEK results in better restoration of vision, the surgical technique is more demanding and may lead to higher levels

of corneal donor loss and primary graft failure. A hybrid technology, ultra-thin DSAEK, is now available that combines the functional advantages of DMEK with the established safety of DSAEK. In ultra-thin DSAEK, the thickness of the lamellar grafts is 100 microns vs. 200 microns in standard DSAEK grafts. Early clinical studies with ultra-thin DSAEK show promising results, but preparation of the pre-cut ultrathin lamellar disks involves the use of a mechanical microkeratome to make a second cut or a femtosecond laser microkeratome which will generate additional costs per patient.

A randomized clinical trial will evaluate ultra-thin DSAEK as compared to standard DSAEK to demonstrate whether this innovation is effective and cost-effective.

Study design

Measurements are performed before and 3, 6 and 12 months after the intervention

Intervention

The intervention consists of the performance of standard DSAEK or ultra-thin DSAEK.

Contacts

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Eligibility criteria

Inclusion criteria

Patients eligible for DSAEK or ultra-thin DSAEK are patients with:

1. Endothelial dysfunction caused by Fuchs' endothelial dystrophy;

2. A minimum patient age of 18 years;

Exclusion criteria

1. Previous corneal transplantation;

2. Human leukocyte antigen typed keratoplasty;

3. Patients who are unable to communicate properly or to understand instructions.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	66
Type:	Actual

Ethics review

Positive opinion

Date:	14-10-2011
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	NL2957
NTR-old	NTR3104
Other	ZonMw : 80-82305-97-12078
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A