Corneal Transplantation by DMEK - is it really better than DSAEK?

Published: 19-05-2016
Last updated: 20-04-2024

The objective of this trial is to assess the effects and costs of DMEK vs. DSAEK in order to determine whether the new technique is effective and cost-effective over the standard technique.

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

Summary

ID

NL-OMON43481

Source
ToetsingOnline

Brief title
DMEK study

Condition

- Vision disorders
- Eye therapeutic procedures

Synonym
Fuchs' dystrophy; Fuchs' Corneal Endothelial Dystrophy (FECD)

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: ZonMw,Collectebusfondsen

Intervention

Keyword: Descemet Membrane Endothelial Keratoplasty (DMEK), Descemet Stripping Automated Endothelial Keratoplasty (DSAEK), Fuchs Corneal Endothelial Dystrophy (FECD), Multi-center Randomized Controlled Trial

Outcome measures

Primary outcome

The primary outcome measure is best-corrected visual acuity.

Secondary outcome

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.

Study description

Background summary

Corneal transplantation improves vision and quality of life in patients with corneal disease. Currently, the standard of care for patients with Fuchs Endothelial Corneal Dystrophy (FECD) is Descemet Stripping Automated Endothelial Keratoplasty (DSAEK), in which only the posterior layers of the cornea are transplanted. However, visual recovery following DSAEK is suboptimal. Descemet Membrane Endothelial Keratoplasty (DMEK), the latest technique in corneal transplantation involves transplantation of only a monolayer of corneal endothelium and Descemet*s membrane providing the thinnest endothelial graft possible. DMEK has been suggested to result in faster and better visual recovery compared to DSAEK. However, this is based on limited evidence, underscoring the need for a randomized controlled trial (RCT).

Study objective

The objective of this trial is to assess the effects and costs of DMEK vs. DSAEK in order to determine whether the new technique is effective and cost-effective over the standard technique.

Study design

Multi-center, prospective, randomized, controlled, single- blinded, interventional clinical trial.

Intervention

The intervention group will receive cornea transplantation by DMEK. The usual care / control group will receive cornea transplantation by DSAEK.

Study burden and risks

Measurements and examinations are performed before and 3, 6 and 12 months after the intervention. Some of the examinations are not part of standard care, but similar to all of the other examinations they are non-invasive, have no side effects and take a few minutes to perform. In addition, patients will be asked to fill in quality-of-life questionnaires and cost questionnaires.
We believe that DMEK patients will benefit from the study because visual outcomes are expected to be better in these patients. Based on the literature, DMEK is not associated with any health risks additional to those associated with DSAEK (standard care).

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Irreversible cornea decompensation caused by Fuchs Corneal Endothelial Dystrophy
- A minimum patient age of 21

Exclusion criteria

- Ocular comorbities other than cataract
- Previous corneal transplantation
- Human leukocyte antigen (HLA) matched keratoplasty
- Inability to complete follow-up

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: Recruitment stopped

Start date (anticipated):	30-09-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-06-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-01-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL55972.068.15
Other	nog niet bekend.