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

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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**

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## **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

CCMO Other ID

NL55972.068.15 nog niet bekend.