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

Published: 23-01-2012
Last updated: 01-05-2024

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.

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

Summary

ID

NL-OMON39225

Source
ToetsingOnline

Brief title
Ultra-thin DSAEK study

Condition

- Vision disorders
- Eye therapeutic procedures

Synonym
Corneal endothelial failure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: ZonMw DO,Stichting Nederlands Oogheelkundig Onderzoek;Dr. F.P. Fischer-Stichting;Landelijke Stichting voor Blinden en Slechtzienden

Intervention

Keyword: DSAEK, Lamellar keratoplasty, Ultra-thin DSAEK, Visual acuity

Outcome measures

Primary outcome

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 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 may result in better visual outcomes and, consequently, a better quality of life.

Study objective

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.

Intervention

The intervention consists of the performance of standard DSAEK (grafts of approximately 200 microns) or ultra-thin DSAEK (grafts of approximately 75 microns).

Study burden and risks

Measurements and examinations are performed before and 3, 6 and 12 months after the intervention. Normally, most of the examinations are not performed at 3 months. All other measurements are part of the standard of care in corneal transplantation. All examinations 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 ultra-thin DSAEK patients will benefit from the study because visual outcomes are expected to be better in these patients.

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

Endothelial dysfunction caused by pseudophakic or aphakic corneal edema, (Fuchs*) endothelial dystrophy, a minimum patient age of 18 years, and best spectacle-corrected visual acuity (BSCVA) lower than 20/50.

Exclusion criteria

Previous corneal transplantation, human leukocyte antigen typed keratoplasty, and 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):	05-06-2013
Enrollment:	58
Type:	Actual

Ethics review

Approved WMO

Date:	23-01-2012
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-07-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-08-2013
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	NL38365.068.11

Study results

Date completed:	01-10-2015
Actual enrolment:	66