Secondary macular edema after Descemet*s Stripping Automated Endothelial Keratoplasty (DSAEK): a prospective, non-comparative study.

Published: 18-09-2008
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Quantification of the incidence of postoperative CME in DSAEK patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32110

Source
ToetsingOnline

Brief title
Post-DSAEK CME

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
macular edema

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis Prof. Dr. H.J. Flieringa.

Intervention

Keyword: cystoid macular edema, DSAEK, optical coherence tomography, risk factors

Outcome measures

Primary outcome

Incidence of CME at 1, 3 and 6 months after DSAEK.

Secondary outcome

Relationship risk factors and pre-op macular condition with post-op CME.

Study description

Background summary

Macular edema (ME) is a possible complication following keratoplastic surgery which affects visual acuity outcome. Because DSAEK has been introduced relatively recently, the incidence of ME and its effect on longterm outcome remains largely unknown.

Study objective

Quantification of the incidence of postoperative CME in DSAEK patients.

Study design

Prospective, non-comparative trial.

Study burden and risks

Study-related measurements will be performed at the time of regular clinical visits, and will take about 50 minutes extra time. Participants do not benefit from study results. Risks are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age >= 18 years of age
- informed consent
- Fuchs* endothelial dystrophy or Pseudophakic Bullous Keratopathy requiring DSAEK
- cornea that allows preoperative OCT imaging
- pseudophakic

Exclusion criteria

- previous ocular surgery that could influence visual outcome
(except uneventful cataract surgery)
- other macular or inflammatory disease that could influence the incidence of CME
(eg. diabetic retinopathy, diabetic maculopathy, retinal vein occlusion, uveitis)
- ocular disease that could influence visual outcome
(except Fuchs`endothelial dystrophy or PBK)
- other ocular surgery planned within 12 months following inclusion in this study
- systemic therapy that could influence the occurrence of macular edema
(eg. Avandia, Acetazolamide)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2009
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	18-09-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL23536.078.08