Assessment of corneal endothelial cell density: automated and manual measurements with specular photography compared to manual measurements with the confocal microscope.

Published: 09-10-2014
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To demonstrate equivalence for ECD between Topcon SP-1P Specular microscope and Nidek Confoscan 4.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Eye disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON40876

Source
ToetsingOnline

Brief title
Endothelial cell counts

Condition

- Eye disorders NEC

Synonym
Fuchs endothelial dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Keyword: DSAEK, endothelial cell density (ECD), Nidek Confoscan 4, Topcon SP-1P

Outcome measures

Primary outcome

ECD

Secondary outcome

Level of agreement (LOA).

Coefficient of variance (CV).

Average cell size (ACS).

Hexagonality.

Study description

Background summary

The endothelial layer is vital for the condition of the cornea, and in particular with disorders such as Fuchs Endothelial Dystrophy monitoring of cell density is important. Unfortunately, however, convenience and reliability of various methods to count endothelial cells do not coincide. In this study the reliability of a new type of specular microscope will be compared to confocal microscopy.

Study objective

To demonstrate equivalence for ECD between Topcon SP-1P Specular microscope and Nidek Confoscan 4.

Study design

Prospective observational study.

Study burden and risks

Patients who are scheduled for a routine 6 months follow-up visit will be asked to undergo two additional measurements, one of which (confocal microscopy) will be *contact* in nature (touching the cornea). Participants do not benefit. Information obtained in this study may help to improve monitoring of the outcome of DSAEK.

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.
Informed consent.
DSAEK performed.

Exclusion criteria

History of a intraocular glaucoma implant (e.g. Baerveldt).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-04-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	09-10-2014
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	NL50105.078.14