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 Last updated: 22-04-2024

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

2 - Assessment of corneal endothelial cell density: automated and manual measurement ... 5-05-2025

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

Public

Oogziekenhuis Rotterdam

Schiedamse Vest 180 Rotterdam 3011 BH NL

Scientific

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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