Collection of normative data of intracorneal reflectivity assessed by in vivo confocal microscopy.

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Collection of baseline features, by in vivo confocal microscopy, of the normal cornea with respect to corneal reflectivity and pachymetry.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30301

Source
ToetsingOnline

Brief title
In vivo confocal microscopy of the normal cornea.

Condition

- Other condition

Synonym
Reflectivity of healthy cornea.

Health condition

Geen: het onderzoek betreft de gezonde cornea.

Research involving
Human

Sponsors and support

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

Intervention

Keyword: confocal microscope, cornea, normative data

Outcome measures

Primary outcome

Mean and variance of corneal reflectivity and width.

Secondary outcome

Reproducibility, inter-researcher variability, age-relatedness.

Study description

Background summary

Many studies have been, and still are, performed to monitor the effects of an intervention or corneal pathology with the help of in vivo confocal microscopy. Although, basic knowledge about the normal cornea should be the standard by which these observations must be compared, the data reported in literature are far from complete. The aim of this study is to get a more comprehensive set of fundamental data acquired by confocal microscopy of the normal cornea.

Study objective

Collection of baseline features, by in vivo confocal microscopy, of the normal cornea with respect to corneal reflectivity and pachymetry.

Study design

Cross-sectional survey.

Study burden and risks

Volunteers will be recruited from patients visiting the Rotterdam Eye Hospital who have healthy corneas. Measurements will take place in course of a number of

sessions, group 1: 4X (months 1, 3, 6, and 9), group 2: 4X (with 3 hour intervals on a single day). During the first session, in any case, measurements will be performed 3 times in succession (learning curve). During the following three sessions it may prove necessary to repeat measurements as well. On average, each session will last about 30 minutes. Pachymetry will be performed in the *contact-mode* with an immersion substance between the microscope*s objective and the corneal surface. Application of a local anaesthetic (eye drops) will minimize discomfort. Risks are considered negligible. Participants do not benefit from this study.

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy cornea, i.e.:

1. Corneal epithelium is intact.
2. Stroma is clear.
3. Endothelium has a regular aspect.
4. No corneal scar(s).
5. No indication for inflammatory processes.
6. No previous surgical intervention.

Exclusion criteria

Ocular trauma,
Intraocular surgery.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2007
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	09-01-2007
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	NL14518.078.06