Investigation of the refractive properties of healthy human eyes and eyes of cataract surgery patients

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Assess raytracing algorithms in determining the refractive properties of the eye. This method is also applied to cataract patients and, therefore, a secondary objective is to determine the effects of surgical incisions on ocular refractive...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular structural change, deposit and degeneration NEC
Study type	Observational non invasive

Summary

ID

NL-OMON39564

Source
ToetsingOnline

Brief title
Ray tracing cataract

Condition

- Ocular structural change, deposit and degeneration NEC

Synonym
cataract

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting wetenschappelijk onderzoek Oogziekenhuis.

Intervention

Keyword: cataract, intraocular lens, refraction

Outcome measures

Primary outcome

Refractive error of the eye, corneal aberrations (both lower and higher order)

Secondary outcome

Effect of surgery on corneal refractive properties.

Study description

Background summary

In cataract surgery, IOL power is predicted based on biometric measurements of the eye. Current methods for determining IOL power in cataract surgery result in 45% of patients having an absolute refractive error greater than 0.5 diopter (D) after surgery. With improvements in the accuracy of biometric measurements, raytracing algorithms to determine IOL power has the potential to improve refractive outcomes after surgery.

Study objective

Assess raytracing algorithms in determining the refractive properties of the eye. This method is also applied to cataract patients and, therefore, a secondary objective is to determine the effects of surgical incisions on ocular refractive properties.

Study design

Observational study.

Study burden and risks

This a non-invasive study. Risks are negligible and burden is low. Total time required for excusively study related assessments in the cataract group (2 extra visits) is 4 X 30 = 120 min. Measurements in the normal subjects group require a single visit of 1 hour.
Measurements for group 4 (taking 1 hour) will be performed only once, in

combination with a regular control visit.

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

Informed consent.
Age >= 18 years.
Only people with a healthy cornea will take part in the study.

Exclusion criteria

Patients experiencing complications during surgery will be excluded from the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2012
Enrollment:	255
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-12-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-04-2014
Application type:	Amendment
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	NL37407.078.11