

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Ocular structural change, deposit and degeneration NEC
<b>Study type</b>	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 exclusively study related assessments in the cataract group (2 extra visits) is  $4 \times 30 = 120$  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

### Public

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Schiedamse Vest 180  
Rotterdam 3011BH  
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

Informed consent.

Age  $\geq 18$  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