Straylight as an additional indicator in surgical refractive procedures.

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To evaluate whether straylight assessments [log(s)] can contribute to develop/refine the decision tree for the indications AC-PIOL, RLE or CE.

Ethical review	Approved WMO
Status	Pending
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36178

Source
ToetsingOnline

Brief title
Straylight and surgical refractive procedures.

Condition

- Vision disorders

Synonym
refractive error

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anterior Chamber Phakic Intra-Ocular Lens, Refractive Lens Exchange, Straylight

Outcome measures

Primary outcome

Straylight parameter s (logs[s])

Corrected distance visual acuity (CDVA), monocular and binocular

Contrast sensitivity

Secondary outcome

Optical characteristics of the eye.

Outcome of questionnaires.

Study description

Background summary

Various means for the correction of refractive errors, including surgical procedures, are available nowadays. In the absence of early cataract, phakic intraocular lens (PIOL) implant is one of the suited procedures, whereas in the presence of early cataract, refractive lens exchange (RLE) is suited. The absence or presence of early cataract is assessed by ophthalmologists using slitlamp examination and classical parameters of visual function (visual acuity [VA] and contrast sensitivity [CS]). However, subclinical lens opacities may not be identified by slitlamp examination. Although these subclinical opacities may already cause a functional effect, it may not yet affect VA and CS tests. However, it may already affect the straylight parameter. In the presence of early cataract there may be a discrepancy between ophthalmologist's assessment of the degree of cataract and the patient*s subjective complaints (e.g. functionally insignificant versus significant cataract). The main cause for such a discrepancy is glare caused by forward light scatter (i.e. straylight). Improvement of visual function after refractive correction may, in part, be due to a reduction of straylight after replacement of the lens, together with its opacities. It is expected that straylight measurement can be used to distinguish the relative contribution of refractive error and glare to visual function impairment.

Study objective

To evaluate whether straylight assessments [log(s)] can contribute to

develop/refine the decision tree for the indications AC-PIOL, RLE or CE.

Study design

Prospective observational case series (pre-post design)

Study burden and risks

Participants do not benefit. Risks are negligible. Patients will be subjected to study-related measurements twice (i.e. pre- and postoperatively). Measurements will be performed at the time of regular visits to Focus Clinic/The Rotterdam Eye Hospital. For the straylight measurements pupils will be dilated by eyedrops. On average, the extra time required will be 1 hour every 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

Age > 18 years
Informed consent
Bilateral refractive treatment

Exclusion criteria

Ocular pathology other than lens opacities (e.g. cornea opacities,)
Per- or postoperative complications
Posterior capsule opacification
Linguistic barrier

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2011
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-06-2011
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	NL36666.078.11