Evaluation of the optical effects of healthy and diseased ocular anterior segment structures on quality of vision

Published: 18-11-2015
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To document mean and range of straylight values in patients with anterior segment disorders possibly under several visual angles

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

Summary

ID

NL-OMON44740

Source
ToetsingOnline

Brief title
Optical effects of the ocular anterior segment

Condition

- Vision disorders

Synonym
diminished quality of vision, straylight

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ocular anterior segment, Optical effects, Quality of vision, Straylight

Outcome measures

Primary outcome

The amount of straylight (mean and range) in patients with anterior segment

disorders.

Secondary outcome

Not applicable.

Study description

Background summary

When a patient visits an ophthalmologist, usually only visual acuity is measured, but quality of vision is influenced by more aspects than visual acuity alone. One of these aspects is straylight. Straylight is the cause of disability glare, hindrance by oncoming headlights, hazy vision and loss of colour and contrast vision. Straylight is caused by intraocular scattering of the light due to disturbances in the ocular media. This scattering of light results in a veil of light over the retinal projection. Recent research has shown that straylight and visual acuity contribute equally to quality of vision.
Patients with ocular anterior segment disorders often complain of reduced quality of vision, but visual acuity may remain at a normal level, causing patients to feel misunderstood. It is possible that an increased amount of straylight contributes to the complaints of these patients. The effect of the (ab)normal anterior segment on visual quality is not yet sufficiently investigated.
Until recently there was no reliable and reproducible method for straylight measurement. In June 2005 a new instrument, the Oculus C-Quant, became available. With this instrument the amount of intraocular straylight can be documented quantitatively. This instrument is suitable for clinical use, as the measurement is non-touch and takes about ten minutes. Currently, straylight measurements are considered one of the standard ophthalmological examinations.

Study objective

To document mean and range of straylight values in patients with anterior segment disorders possibly under several visual angles

Study design

- observational case series of quality of vision in patients with anterior segment disorders

Intervention

Patients with dry eyes will undergo the following examinations:
1) documenting subjective complaints of reduced visual quality
2) measurement of best corrected visual acuity
3) straylight measurement and measurement of the natural pupil diameter
4) standard slitlamp investigation, with special attention for the tear break-up time and damage to the anterior ocular segment (conjunctiva and cornea) by dry eyes
5) schirmer test (meaurement of aqueous tear production)
(all examinations are standardly performed on patients with dry eyes visiting the outpatient clinic of the department of Ophthalmology)
2) a pilot study will be performed on volunteers and will consist of the following:
- the tear film will be made extremely turbid with the use of coffee creamer; the visual effect will be measured with straylight measurements performed just before the use of coffee creamer and during the 'wash out'-period
- with the use of an eyelid speculum the tear break-up time will be lengthened to a maximum of 10 minutes (normal tear break-up time is 10 to 15 seconds); the visual effect of this lengthened tear break-up time will be measured with straylight measurements peformed at regular intervals during the time the eyelid speculum is in situ.
- the visual effect of four commercially available lubricants (Hylocomod eyedrops, optive eyedrops, liposic eye gel and oculentem simplex ointment) will be measured by straylight measurements performed before the administration of the lubricants and immediately after administration, as well as 10 minutes, 30 minutes and 60 minutes later.

Study burden and risks

The measurements will take place during a single visit to the outpatient clinic of the department of Ophthalmology and will take approximately 1 hour.
No risk is attached to the measurements; the chance of ocular damage or side effects is practically non-existent.

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

For patients:
1. Subjective straylight complaints, or the presence of an ocular anterior segment disorder which can be the cause of increased straylight.
2. Able to understand the study information and willing to give informed consent.

Exclusion criteria

Ocular posterior segment pathology which can affect the straylight measurements

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	18-11-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL40857.018.15