

Influence of diseased anterior segment on ocular straylight and the relation to vision related quality of life

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Eye disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49252

Source

ToetsingOnline

Brief title

Straylight and Quality of Life

Condition

- Eye disorders

Synonym

and lens of the eye, iris, Ocular anterior segment disease; Disease of the cornea

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anterior segment, Straylight

Outcome measures

Primary outcome

Correlation of change in straylight after treatment of anterior segment disease and vision related quality of life questionnaire.

Secondary outcome

- Correlation of straylight with glare complaints questionnaire
- Pupil dependence of straylight in anterior segment disease

Study description

Background summary

Previous research has been performed on the factors involved in the physical properties of straylight and clinical implications in certain ocular anterior segment pathologies. It is known that straylight is formed by imperfect optical media through which light is scattered onto the retina. The light distribution on the retina is described with the point-spread-function, and the scattered light primarily involves the area outside the 1° core, thus having little effect on high-contrast measures of central visual acuity. The retinal light distribution leads to the visual phenomenon of light spreading seen around bright lights. This is called straylight.

Ocular straylight as observed by the patient can be measured using the non-invasive Oculus C-Quant device; straylight induced by a blinking circle is compared by the patient in blinking intensity to a light source of which the intensity is known. As the sources are indistinguishable except for blinking intensity, a reliable measurement can be made within about 1.5 minutes.

Anterior segment diseases that create imperfect ocular media such as cataract and corneal scarring have been found to increase straylight independently of affecting visual acuity. In cataract surgery straylight is found to have an equal effect as visual acuity on quality of life on average. However, variation was found to be large. For some patients it is difficult to predict personal straylight levels, and not all patients with high straylight levels mention

complaints of glare. Improving knowledge about how straylight levels relate to subjective complaints and vision related quality of life can help improve treatment indications.

An important source of variation may be pupil diameter. It is known that media disturbances are often distributed unevenly across the pupil opening. The importance of this on the recorded straylight levels needs to be established.

Study objective

The goal of the current study is to measure effects of straylight changes after treatment of anterior segment disease and the relation to vision related quality of life. A secondary goal is to further investigate the relation to subjective glare complaints and actual straylight levels by use of a straylight questionnaire

Primary Objective: To measure the effect of change in straylight after treatment of ocular anterior segment disease on a vision related quality of life score.

Secondary Objectives:

- To assess the relation of a straylight questionnaire to a vision related quality of life questionnaire and objective straylight scores.
- To assess the pupillary diameter dependency of straylight in eyes with anterior segment disease.

Study design

Prospective observational study, time between measurements for individual participants depends on the waiting list for treatment and can be several months. The full study period will be 2 years.

Study burden and risks

There is no physical risk in all examinations performed. Participants may experience distress from straylight results that are not within expectations. There is no direct benefit for participants and no change in clinical treatment related to the outcomes.

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

- Be 18 years of age or older
- Capable of giving informed consent
- Able to undergo straylight measurement, slitlamp examination, and complete a questionnaire
- Presence of ocular anterior segment pathology including the cornea, anterior chamber, iris, and lens(capsule).
- only for control group: absence of ocular anterior segment disease

Exclusion criteria

- Visual acuity equal to or poorer than 1.00 on the ETDRS logMAR chart
- Inability or unwillingness to giving informed consent

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:	Recruiting
Start date (anticipated):	17-10-2019
Enrollment:	113
Type:	Actual

Ethics review

Approved WMO	
Date:	03-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-09-2020
Application type:	Amendment
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	NL70087.018.19