

Light on glaucoma: pilot study to measure contrast sensitivity, visual field, and adaptation time at high light conditions.

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The objectives of this pilot are (1) to test and develop an experimental setup to determine contrast sensitivity, visual field and adaptation time at high light conditions. (2) To perform a pilot study with 10 healthy subject.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON42361

Source

ToetsingOnline

Brief title

Light on glaucoma: pilot study

Condition

- Glaucoma and ocular hypertension

Synonym

glaucoma, POAG

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: Adaptation time, Contrast sensitivity, Glaucoma, High light conditions

Outcome measures

Primary outcome

Measurement of contrast sensitivity, visual field and adaptation time at high light conditions.

Secondary outcome

N/A

Study description

Background summary

Many patients with glaucoma experience difficulties while seeing in light and dark conditions. These difficulties are not only present in patients with severe glaucoma, but also in patients with a normal visus and an intact visual field. We already researched the influence of light- and dark conditions using a questionnaire (METc 2014/338) and confirmed the difficulties described above. In addition, patients with glaucoma experience longer light- and dark adaptation times compared with healthy subjects. In a former project (METc 2014/409) we researched the influence of static low light conditions and in the project that followed (METc 2015/276) we researched the adaptation time to low light conditions. In the pilot of this application, we continue with the influence of high light intensities on the contrast sensitivity, visual field and adaptation time. There is no literature available of the influence of high light intensities. There is no device available yet to provide these intensities.

Study objective

The objectives of this pilot are

- (1) to test and develop an experimental setup to determine contrast sensitivity, visual field and adaptation time at high light conditions.
- (2) To perform a pilot study with 10 healthy subject.

Study design

Pilot study

Study burden and risks

A single visit, in which the contrast sensitivity, visual field and adaptation time at high light conditions will be measured. There are few extra tests to check the healthy state of the eye. Total time invested 2 hours. It is possible that an eye disease is discovered during the course of this study. The resulting psychological stress to the subject can be a disadvantage. However, the advantage is an early start of adequate treatment. All measurements are conducted using optical techniques that do not touch the eye and therefore are completely harmless. There is no risk during the experiments. No mydriasis (pupil dilation) will be implemented.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy subjects will consist of people (age 18-70) who have signed in, without ophthalmic abnormalities and provide written informed consent.

Exclusion criteria

- Subjects with an eye disease.
- Subjects with a first degree relative with glaucoma, or with high eye pressure in the past.
- Visual acuity below 1.0 (below 50 years of age) or below 0.8 (above 50 years of age).
- Visual field defects which are not understood.

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): 25-04-2016

Enrollment: 10

Type: Actual

Ethics review

Approved WMO

Date: 10-02-2016

Application type: First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	02-05-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
Other	201501071(UMCG Research Register)
CCMO	NL55530.042.15