Light Adaptation in glaucoma- The influence of dynamic light conditions on visual functioning.

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To determine the influence of dynamic light conditions on visual functioning in glaucoma. For this purpose we measure (1) the contrast sensitivity to a small stimuli at a time-varying background luminance and (2) the critical fusion frequency (CFF...

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

Summary

ID

NL-OMON45610

Source
ToetsingOnline

Brief title
Light Adaption in glaucoma

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,European committee

Intervention

Keyword: Contrast sensitivity, Dynamic light conditions, Glaucoma, Light intensities

Outcome measures

Primary outcome

Contrast gain control as a function of the frequence in which background luminance changes in time. Contrast sensitivity in central and peripheral sites of the retina will be measured by using a staircase method. The contrast gain control will be defined as the difference between the contrast sensitivity measured at static (0 Hz) versus the dynamic light conditions. The contrast gain control can then be compared between the healthy control group and glaucoma patients. We measure contrast gain control at two different values of the mean background luminance and for two polarities (white (increment) and black (decrement) stimuli on a gray background).

Secondary outcome

Critical Fusion Frequency (CFF). CFF is the highest frequency at which flicker can be detected. This will be measured in the central and peripheral visual field for a range of background luminances.

Study description

Background summary

Glaucoma is an optic neuropathy in which a degeneration of retinal ganglion cells results in loss of the visual field and - if left untreated - blindness. Recent studies have uncovered that significant visual complaints exist even if the visual field is still intact or only mildly affected. These complaints are related to light and dark adaptation.

The human retina can adjust its operating range to a wide range of illumination levels. Adaptation refers to both the process of adjustment, that is, adapting to a new condition, and to be adapted to a condition. Previous studies have uncovered that adaptation to different light conditions is disturbed in glaucoma: it is delayed and incomplete.

We aim to extend this research and to determine how patients with glaucoma perform under rapidly varying light conditions. For this purpose we will perform psychophysical experiments with a stimuli presented on a computer screen where either the background luminance or the stimulus itself changes rapidly with time. The former paradigm refers to contrast gain control (the retina*s ability to keep its sensitivity in the presence of changing contrasts); the latter is known as flicker sensitivity.

The measurements will be performed by glaucoma patients (n = 30) and healthy subjects (n = 30) (see 4.4 Sample Size Calculation). By comparing the results for each patient with data from normal observers, we will determine the extent of the visual losses associated with glaucoma, thus yielding new insights of light adaptation dynamics in glaucoma. Subjects with glaucoma will be recruited from a population of glaucoma patients who visit the ophthalmology clinic at the University Medical Center Groningen. For the recruitment of healthy subjects, poster adverts (see Appendix E3) will be placed in and around the UMCG

Study objective

To determine the influence of dynamic light conditions on visual functioning in glaucoma. For this purpose we measure (1) the contrast sensitivity to a small stimuli at a time-varying background luminance and (2) the critical fusion frequency (CFF), which is the highest frequency of flicker that can be distinguished from steady state (temporal sensitivity).

Study design

Case-control study

Study burden and risks

Patients and healthy subjects will have one visit to the Laboratory of Experimental Ophthalmology to perform psychophysical experiments . Healthy subjects will undergo screening to assess their eye health, which will comprise a questionnaire (see Appendix F1), letter chart, visual field test, optical coherence tomography (OCT) test of retina and optic nerve head, and intraocular pressure (IOP) measurement. Screening will take around 20 minutes. The eye will not be touched during screening, nor are mydriatic drugs required for pupil dilation. If abnormal screening results are obtained for healthy subjects, they

will be referred to their GP. Dtection of an eye condition may cause psychological stress, however, an early diagnosis will allow treatments to be initiated and therefore more preservation of visual functioning. Glaucoma patients will not perform any screening tests, therefore there is no risk of ientifying any other eye conditions. Subjects with glaucoma will be recruited froam a population of glaucoma patients who visit the ophthalmology clinic at the UMCG. For the recruitment of healthy subjects, poster adverts (see Appendix E3) will be placed in and around the UMCG. Patients and healthy subjects will spend 1.5 and 2 hours in our lab, respectively, to complete the required tasks.

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

Glaucoma patients between ages 50 and 75, who visit the Ophthalmology clinic at University

Medical Center Groningen, that have provided the informed consent form and meet the inclusion-exclusion criteria.
Healthy subjects between ages 50 and 75, who have provided the informed consent form and returned the questionnaire with results which do not indicate ophthalmic abnormalities.

Exclusion criteria

Glaucoma Patients:
Visual acuity less than 0.8
Non-glaucomatous visual field loss;Healthy Subjects:
Visual acuity less than 0.8
Any visual field loss
Intraocular pressure above 21 mmHg
Positive family history of glaucoma

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:	Recruitment stopped
Start date (anticipated):	22-08-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	24-05-2017
Application type:	First submission
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

ID: 29472
Source: NTR
Title:

In other registers

Register	ID
Other	n/a
CCMO	NL61403.042.17
OMON	NL-OMON29472