Glaucoma screening during regular optician visits, the specificity of screening in real life.

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Primary Objective: The aim of this study is to determine the specificity in *real life*, when screening is performed during regular optician visits. This specificity will depend on the specificity of the screening test, the frequency of other eye...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glaucoma and ocular hypertension
Study type	Interventional

Summary

ID

NL-OMON35486

Source
ToetsingOnline

Brief title
Glaucoma screening during regular optician visits.

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Intern onderzoeksbudget afdeling oogheelkunde UMCG

Intervention

Keyword: Frequency Doubling Perimeter (FDT), glaucoma, screening, specificity

Outcome measures

Primary outcome

For the outcomes of both questionnaires (optician/hospital) and the results of

the additional tests descriptive statistics will be used.

Secondary outcome

Not applicable.

Study description

Background summary

The aim of Vision 2020 (Netherlands), a project of the World Health Organization (WHO), is to exterminate preventable blindness throughout the world (The Netherlands) in 2020. Glaucoma is a chronic-progressive disease which eventually can lead to blindness. Throughout the world glaucoma is the second cause of avoidable blindness (Kingman S, 2004). Early stages of glaucoma often remain unnoticed. Treatment can slow down or even stop the process. Screening for glaucoma could therefore be useful. At this moment there is no systematically screening programme for glaucoma in The Netherlands. It appears that approximately half of the patients with glaucoma are undetected at a certain moment (Hollows and Graham 1966; Wolfs et al. 2000). This can be a reason to perform screening but on the other hand recent investigation showed that about 1000 glaucoma screening tests would have to be performed in order to prevent one case from becoming blind during live (many glaucoma patients pass away before they become totally blind, even when they remain untreated). To prevent unilateral loss of vision, about 200 tests should be done (Stoutenbeek et al. 2008). A nationwide population based screening for glaucoma is not automatically cost-effective, therefore we are also investigating other options including screening during regular optician visits. Another study from our research group showed that 80% of the population who are at risk for glaucoma, visit an optician at least once in 5 years, and 84% is going to an optician or ophthalmologist at least once in 5 years (Stoutenbeek and Jansonius 2006). The same study showed that of the opticians who answered a questionnaire about

participation in a glaucoma screening programme, 91% were willing to participate. At this time, most opticians perform glaucoma screening by measuring the intraocular pressure (the main risk factor for glaucoma). However, additional tests are necessary because previous investigation showed that only half of the patients with glaucoma showed an increased intraocular pressure at a single measurement (Katz et al. 1993), and it appeared that a lot of newly-diagnosed glaucoma patients recently visited an optician where the diagnosis glaucoma was not made. A study of GrØdum et al. showed that also many glaucoma patients are overlooked in routine clinical ophthalmological practice (GrØdum et al. 2002).
To further explore the feasibility of glaucoma screening in the Netherlands, two studies will be performed. In the first study, the severity of glaucoma, at the time patients are detected nowadays, will be investigated. In the second study, a protocol for glaucoma screening by opticians will be introduced and the specificity in *real life* will be calculated. The first study serves as a baseline measurement that should enable the evaluation of the introduction of screening in the future. This protocol describes the second study.

Study objective

Primary Objective:
The aim of this study is to determine the specificity in *real life*, when screening is performed during regular optician visits. This specificity will depend on the specificity of the screening test, the frequency of other eye diseases detected by this protocol and the skills of the optician. The subjects with an abnormal screening test result will be divided in patients with glaucoma (true positives) and patients without glaucoma (lfalse positives) The latter group can be divided in subjects without any eye disease and subjects with another eye disease (for example, cataract).

Secondary Objective(s):
Do these patients have risk factors for developing glaucoma?
Is (more) training/education needed for opticians?
How is the cooperation between opticians and ophthalmologists, are improvements possible?

Study design

Study: Intervention study.

Duration: 1 year.

Setting of the study: Opticians will receive a protocol to screen patients for glaucoma. All regular visitors >= 45 years will be screened. When a person is referred to the hospital because of suspected glaucoma, additional tests will be performed:

- Refraction (best corrected visual acuity): measured with a letter chart.

- GDx test: to measure the thickness of the retinal nerve fibre layer, patients have to look into the lens of the camera and will see during a few seconds a weak red background. A few images of each eye will be made and these will be analysed against a database on the machine to see if the results are in the normal range.

- Fundusphotography: the pupils of the eyes will be dilated with tropicamide 0,5 % and phenylerfrine 2,5% to allow us to get a good view of the back surface of the eye. Once these drops are working, the patient places the chin on a chin-rest and the camera is brought into place in front of the eye. The patient will see a bright flash each time we take an image, which can dazzle the eyes for a few minutes afterwards. Several images will be captured.

- Non-contact tonometry: or air-puff tonometry uses a rapid air pulse to applanate the cornea. Corneal applanation is detected via an electro-optical system. IOP is estimated by detecting the force of the air jet at the instance of applanation. The patient places their chin on a chin-rest and needs to stair straight ahead for the measurement. The IOP will also be measured by applanation tonometry where a special desinfected prism is mounted on the tonometer head and then placed against the cornea.

- The central corneal thickness will be measured using pachymetry. Measurements are taken by placing an anesthetic drop (oxybuprocaïne 0.4%) on the eye and gently touching the probe to the surface of the cornea. Three measurements will be done of which the mean will be calculated.

- Standard automated perimetry (suprathreshold Humphrey Field Analyzer [HFA]): after the patient has placed the chin on a chin-rest, a serie light stimuli on a bowl-shaped screen is presented. The lights vary in brightness and will appear in different positions in the field of view. There will be asked to press a button each time a point of light is seen which the machine records. The machine checks each point several times. The test will be performed for each eye separately and the fixation will be tested previously. A print- out will show the retinal sensitivity for different locations of each eye.

A questionnaire will be completed by the optician, about whether the visitor has undergone glaucoma screening and if referral to the ophthalmologist is necessary.

When a person arrives at the hospital a few questions will be asked concerning the reason for visiting the optician, eye symptoms and risk factors for developing glaucoma, before the additional investigation will take place.

Intervention

Look at box: "study design".

Study burden and risks

It is possible that another disease will be discovered during the course of this study. The, consequently, psychological distress for the patient can be a disadvantage. The advantage will be, because of this (early) detection that treatment can start immediately.

The eye drops that provide pupil dilation ensures that the patient sees several hours less sharp. In the informationletter it is recommanded not to drive or cycle the first hours. The advice is given to go home under supervision.

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

Men and women >= 45 years who are consecutive optician shop visitors. Patients who are not screened by means of the protocol or patients who are already diagnosed with glaucoma will also be counted.

Exclusion criteria

Men and women < 45 years. Patients who are already diagnosed with glaucoma will be counted, but will not undergo glaucomascreening.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-03-2010
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	01-03-2010
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

No registrations found.

In other registers

Register	ID
CCMO	NL29602.042.09