Clinical evaluation of eye-movement perimetry in glaucoma

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To determine the diagnostic performance (sensitivity, specificity, and area under the ROC curve) of the current eye-movement based perimetry techniques, SONDA and BulbiCAM, as potential screening instruments for glaucomatous VF defects in ophthalmic...

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

Summary

ID

NL-OMON57049

Source
ToetsingOnline

Brief title
Glaucoma screening with eye-movement perimetry

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: Visio Foundation;zonMW programma Expertisefunctie Zintuiglijk Gehandicapten (subsidienummer 637005001 en Uitzicht (subsidienummer UZ2019-20) via fondsen beschikbaar gesteld door ANVVB;Oogfonds;Stichting blindenpenning;LSBS

Intervention

Keyword: Diagnostic performance, Eye movements, Glaucoma, Perimetry

Outcome measures

Primary outcome

Diagnostic performance: sensitivity, specificity, and the area under the

receiver-operating characteristic (ROC)-curve of the SONDA and the BulbiCAM

The output of the feedback questionnaire for each perimetric technique.

Secondary outcome

N/A

Study description

Background summary

Glaucoma is a chronic eye disease that eventually can lead to irreversible blindness. Visual field (VF) testing is an important tool for detecting, characterising and monitoring vision loss in glaucoma. The current gold standard to measure the visual field is standard automated perimetry (SAP). This technique requires prolonged focussed attention, understanding of the test, and multi-tasking. These requirements exclude valid and reliable use of SAP in very young and very old persons or persons with cognitive and/or motor impairments, critically limiting the quality of vision care and rehabilitation services such persons should receive. Eye-movement based techniques for perimetry are a potential alternative to SAP as these do not require manual responses and simplify the approach. In particular eye-movement based responses can be used to detect glaucomatous visual field defects via slowed saccadic reaction times to peripheral targets (Kadavath Meethal et al., 2018; Mazumdar et al., 2014; McTrusty et al., 2017; Pel et al., 2013). The BulbiCAM (BulbiTech AS, Trondheim, Norway) performs eye-movement perimetry by measuring saccadic reaction times to peripherally presented targets. It uses a virtual reality (VR) headset that measures both eyes separately as each eye looks at a different screen. Recently, we took a distinctive approach towards eye movement perimetry with the Eye-Movement Correlogram test (SONDA) in which we measure eye-movement based tracking performance of a continuously moving stimulus, shown on a regular display screen while the eyes are being tracked with a remote eyetracker. In an earlier study (Study ID: NL70382.042.20; METc

2020/043) we have optimised this stimulus (Vrijling, de Boer et al 2023) and we have shown that glaucomatous VF defects affect the tracking performance. The results indicate that the SONDA can potentially be used as a fast and reliable perimetric screening method for glaucoma in regular ophthalmic care. If proven to be true, this could be an important development to improve vision care. Therefore, to further this use of eye-movement based perimetry approaches in clinical care, in this study, we aim to validate both the SONDA and the BulbiCAM in a large, independent sample of glaucoma patients and age-matched control participants in order to determine their diagnostic performance. And we will determine the user friendliness for each perimetric technique with a feedback questionnaire.

Study objective

To determine the diagnostic performance (sensitivity, specificity, and area under the ROC curve) of the current eye-movement based perimetry techniques, SONDA and BulbiCAM, as potential screening instruments for glaucomatous VF defects in ophthalmic practice.
To determine the userfriendliness of the perimetric techniques (feedback questionnaire)

Study design

Observational case-control study.

Study burden and risks

The SONDA and the BulbiCAM tests themselves are very simple to perform; the task for the participant consists of following a moving and jumping dot on a screen with one*s eyes for the SONDA, and looking at appearing dots for the BulbiCAM while the eye movements are tracked with an eyetracker. Total testing takes at most 20 minutes (about 6-7 minutes per technique; for the SONDA we use two versions: our experimental setup (SONDA-Eyelink) that was used to develop the technique and a prototype of a version suitable for future clinical use; SONDA-Neon). In addition, for control participants only, a short eye-health check of approximately 20 minutes is performed to ensure eye-healthiness.

Participants will be made aware that they can refuse or end participation in the study at any time. For all control participants: if any abnormal screening results are obtained in the short eye-health check, they will be referred to their GP. Detection of signs of an eye condition may come as an unexpected, unpleasant surprise, however, an early diagnosis will allow treatments to be initiated and therefore enable more preservation of visual functioning.

All participants will be asked to fill out a feedback questionnaire (see form F1b), that will be used to qualitatively evaluate the user friendliness of each

perimetric technique.

Total test time and location:
- glaucoma patients: 20 minutes
- control participants: 40 minutes (including a short eye-health check of approximately 20 minutes

The eye-health check will be conducted at the Ophthalmology Outpatient Clinic, UMCG Groningen. The SONDA and the Bulbicam will be conducted at the Laboratory for Experimental Ophthalmology, UMCG Groningen

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

Control participant:
- Visual Acuity (best corrected) 0.30 logMAR (or better)
- Age: 18-80 years
- Informed written consent

Participant with glaucoma:
- Diagnosed with glaucoma including glaucomatous visual field loss on SAP
- Visual Acuity (best corrected) 0.3 logMAR (or better)
- Age: 18-80
- Informed written consent

Exclusion criteria

Control participant:
- eye disease (not including glasses or uncomplicated cataract surgery
- abnormal OCT
- family history of glaucoma (father, mother, brother or sister with glaucoma, or if the person has ever had a high eye pressure measured)
- neurological disorder that may influence the visual field or eye movements (such as a stroke, MS or Parkinson*s Disease)

Participant with glaucoma:
- neurological disorder that may influence the visual field or eye movements

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):	09-01-2024
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	BulbiCAM
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-11-2023
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
Other	17292 (PaNaMa)
CCMO	NL84477.042.23