Perimetry based on eye-movements in patients with ABI and Glaucoma - a screeningtest using eye tracking

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1. Optimize the EMC-test*s potential to predict the SAP-parameter Mean Deviation (MD), based on simulated visual field defects in healthy observers.2. Refine the EMC-test*s potential to predict the SAP-parameter MD in patients.

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

Summary

ID

NL-OMON49523

Source
ToetsingOnline

Brief title
Promise

Condition

- Other condition
- Glaucoma and ocular hypertension

Synonym
Glaucoma, POAG. Acquired brain injury; Brain disease

Health condition

niet- aangeboren hersenletsel

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Novum

Intervention

Keyword: Acquired brain injury, Eye tracking, Glaucoma, Perimetry

Outcome measures

Primary outcome

The main endpoints of the study are the validity and the test-retest

reliability of the EMC-test:

1. convergent validity: difference (dB) between the predicted MD (EMC) and the

assessed MD (SAP), expressed as delta MD.

2. test-retest reliability: the variability of the predicted MD (dB) between

consecutive measurements in the same person

Secondary outcome

N/A

Study description

Background summary

An intact visual field is extremely important for daily functioning. For instance, it is a prerequisite to be allowed to drive a car, for instance. The current gold standard to measure the visual field is by means of standard automated perimetry (SAP). This technique requires prolonged focussed attention, understanding of the test and multi-tasking. This precondition excludes valid and reliable use of SAP in 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. A breakthrough for these persons and their care would be a short perimetric screening test that requires minimal effort and attentional focus. A recently developed eye-movement-based perimetric screening test (EMC-test), holds great promise

towards this aim. Therefore, we hypothesise that the EMC test overcomes the limitations of SAP. The Promise study will evaluate this in two patient groups. However, before it can be incorporated into daily care and services, the EMC*s capabilities need to be investigated further. In particular, we need to determine how its outcomes relate exactly to those of SAP. This is the aim of the present study.

Study objective

1. Optimize the EMC-test*s potential to predict the SAP-parameter Mean Deviation (MD), based on simulated visual field defects in healthy observers.
2. Refine the EMC-test*s potential to predict the SAP-parameter MD in patients.

Study design

Multiple observational case-control studies.

Study burden and risks

The EMC test itself is very simple to perform, and exists of following a moving and jumping dot on the screen with one*s eyes for 20 secs at a time while we track the eyes with a remote eyetracker. In addition, a calibration of the tracker is required. Total testing takes on average about 10-15 minutes. In addition, a number of standard ophthalmic tests are performed.
The total test time and location for each group is summarized below.

Total test time and test location per experiment.
Experiment O1-5: Healthy control participants (n=5x20); Total test time Visit: 165 minutes; Location: UMCG, Ophthalmology Outpatient Clinic
Experiment A1: Healthy control participants (n=45); Total test time Visit 1: 120 minutes; Visit 2: 45 minutes; Location: UMCG, Ophthalmology Outpatient Clinic
Experiment A2 Glaucoma patients (n=45); Total test time Visit 1: 60 minutes; Visit 2: 15 minutes; Location UMCG, Ophthalmology Outpatient Clinic
Experiment A3 ABI patients with CI, without VFD (n=15); Total test time Visit 1: 105 minutes; Visit 2: 60 minutes; Location: UMCG, Ophthalmology Outpatient Clinic
Experiment A4 ABI patients without CI with VFD (n=15); Total test time Visit 1: 60 minutes; Visit 2: 15 minutes; Location: UMCG, Ophthalmology Outpatient Clinic.

Participants will be made aware that they can refuse or end participation in the study at any time. For all patients and healthy control participants: If any abnormal screening results are obtained in any of the screenings, they will be referred to their GP. Detection of signs of an eye condition or cognitive impairment may come as an unexpected, unpleasant surprise, however, an early

diagnosis will allow treatments to be initiated and therefore enable more preservation of visual or cognitive functioning.

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

Participant without vision loss (control participant; experiment O, A1)
-18 years or older.
• Informed written consent

Participant with Glaucoma (experiment A2):
•Diagnosed with glaucoma
•Reliable SAP (based on most recent SAP assessment, information in their medical file).

•Age 50-70
•No cognitive impairments (MoCa score: score >= 24; TOSSA screening test score > 5th percentile)
•Informed written consent

Participant with ABI (experiment A3):
•Diagnosed with acquired brain injury
•Cognitive impairment (CI), based on test scores regular care UMCG.
•Age:18-70
•Informed written consent.

Participant with ABI (experiment A4):
•Diagnosed with acquired brain injury
•Age 50-70
•Informed written consent.

Exclusion criteria

Any of the following criteria will lead to exclusion from participation:

Participant without vision loss (healthy control participant; experiment O, A1)
•eye disease
•family history of glaucoma
•neurological disorder
•cognitive impairment: MoCa score: score < 24; TOSSA screening test score < 5th percentile.

Participant with Glaucoma (A2)
-neurological disorder
-cognitive impairment: MoCa score: score < 24; TOSSA screening test score < 5th percentile.

Participant with ABI (experiment A3):
•eye disease
•glaucoma

Participant with ABI (experiment A4):
•eye disease
•cognitive impairment: MoCa score: score < 24; TOSSA screening testscore < 5th percentile.

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):	02-11-2021
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	30-03-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-09-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	11-04-2023
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	202000003
CCMO	NL70382.042.20