The development of a simulator-based driving test for glaucoma patients

Published: 19-12-2011
Last updated: 30-04-2024

To investigate the extent to which performance measurements in a driving simulator discriminate between glaucoma patients and a control group.

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

Summary

ID

NL-OMON35659

Source
ToetsingOnline

Brief title
Driving performance of glaucoma patients

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis Rotterdam.

Intervention

Keyword: Driving performance, Driving simulator, Glaucoma

Outcome measures

Primary outcome

During the test, participants* driving performance (position and speed of the virtual vehicle, control inputs), will be recorded. High-end eye tracking (Smart-Eye) will be applied to record head position and rotation, gaze direction, eyelid opening and pupil size.

Secondary outcome

N.a.

Study description

Background summary

Little is known about the relationship between the structural and functional damage of the nerve fibre layer in glaucoma and vision-related disabilities. In this study we investigate driving simulation as a means to assess visual performance. Driving performance will be correlated to structural and functional clinical parameters.

Study objective

To investigate the extent to which performance measurements in a driving simulator discriminate between glaucoma patients and a control group.

Study design

This study is an explorative study.

Study burden and risks

Participants of this study do not benefit, study procedures are non-invasive and take about 30 - 45 minutes. Patients with a history of motion/simulator

sickness will not be included in the study.

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

General:
Age >= 18 years and < 85 years.
Informed consent.
Drivers* license and minimally three years of driving experience.
Control group:
Normal visual field (VF) in both eyes (i.e. mean deviation and pattern standard deviation within 95% confidence limits, hemifield test within normal limits, no other VF abnormality).
Glaucoma group:
Glaucoma diagnosis (i.e. if two of the following conditions are met: pattern standard

deviation significant at p=0.05, abnormal hemifield test result, cluster of >= 3 points depressed at p=0.05 level or 1 point at p=0.01). VF defects must be reproducible on at least one occasion.

Exclusion criteria

General:
BCVA > 0.3 (LogMAR).
Refractive error ouside -10.0 to +5.0 D range.
Cataract surgery in previous 12 months.
Previous refractive or vitreoretinal surgery.
Evidence of diabetic retinopathy, diabetic macular edema, or other vitreo-retinal disease.
Previous keratoplastic surgery.
Because driving simulators have been associated with simulator adaptation syndrome (SAS), characterized by autonomic symptoms such as drowsiness, vertigo, or nausea during testing participants with a history of motion/simulator sickness will be excluded from this study.
Control group:
Glaucoma.
IOP >= 22 mm Hg.
Untreated occludable angle with iridolenticular contact or evidence of iridolenticular contact or peripheral anterior synechia.
Presence of disc hemorrhage.
Glaucoma group:
Secondary glaucomas except pigmentary.
Evidence of SAP VF abnormality consistent with other disease.

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):	22-12-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL38177.078.11