Assessing fitness to drive in older glaucoma patients

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To examine the OcuDrive test package in glaucoma patients and healthy controls in relation to fitness to drive. The main objective is to find the tests from the package that discriminate best between fit and unfit drivers.

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

Summary

ID

NL-OMON48093

Source
ToetsingOnline

Brief title
OcuDrive2

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: This project has received funding from the European Union□s Horizon 2020 research and innovation programme under the Marie Sk□odowska-Curie grant agreement No 675033

Intervention

Keyword: Fitness to Drive, Glaucoma

Outcome measures

Primary outcome

Driving simulator performance, quantified by the occurrence of crashes as pass or fail.

Secondary outcome

Secondary study parameters/endpoints

Other secondary study parameters are the data gathered with the OcuDrive test package. These variables will be included in the discriminant analysis but will also be compared between fit and unfit group, as determined by driving simulator performance. Lastly, the data from the questionnaires will be analysed to evaluate the differences between those groups.

Other study parameters

Other study parameters include personal data such as age, education and sex. These data will be compared for both groups (glaucoma and healthy controls) to ensure that both groups have similar demographics.

Study description

Background summary

The effects of glaucoma are usually measured with visual field tests. When the visual field defects are mild to moderate driving is still allowed and many glaucoma patients do continue to drive. However, assessing the visual system might be hard to do reliably in older people and it might not be sufficient for

selecting unfit drivers. Therefore, the OcuDrive test package has been composed. The OcuDrive test package assesses the entire neurovisual system, including measures of executive function, processing speed, and attention.

Study objective

To examine the OcuDrive test package in glaucoma patients and healthy controls in relation to fitness to drive. The main objective is to find the tests from the package that discriminate best between fit and unfit drivers.

Study design

A cross-sectional observational study.

Study burden and risks

In this study the participants will receive a small financial compensation of 20 euro*s in the form of a gift certificate for their time and a free test of their visual acuity. The risks of participating are minimal, and the burden of participation is small, since all tests will be done on paper, the computer or the Ocusweep device. The only risk is simulator sickness from driving in the driving simulator. Extra attention will be paid to participants when they are in the driving simulator and after each ride they will be asked how they feel and if they are ready to continue with the next ride. When simulator sickness occurs, and the participants wants to stop, the simulator will be stopped immediately. The total time for a complete assessment will be 3.5 hours, including several breaks. Participants will also fill in a short questionnaire at home before coming to the test location, which will take about 15 minutes.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age over 65 years old
Have a valid driver*s licence or held one until recently (up to six months before the test day)
Visual acuity better than 0.5
Speaks the Dutch language

Exclusion criteria

Motor disorders
Medication use that prohibits driving (IDCATS III)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2019
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Ocusweep
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-02-2019
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	NL67866.042.18
Other	UMCG Research Database: 201800808 & NTR 7576