Dutch Parkinson, Cognition and Driving Ability study part two (DUPARC-drive 2): A study on fitness to drive in early phase Parkinson*s Disease patients.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON50941

Source
ToetsingOnline

Brief title
Fitness to drive in early phase Parkinson's disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognition, Fitness to drive, On-road driving test, Parkinson's Disease

Outcome measures

Primary outcome

The primary endpoint will be a cut-off score on the MoCA which has high, preferably 100% sensitivity and reasonable specificity (>70%) in predicting the failure on the CBR on-road driving assessment.

Secondary outcome

The study sample will be divided into a pass and fail group, based on the on-road driving assessment. Groups will be compared in terms of age, disease severity, and performance on motor-, cognitive- and driving simulator tests. In addition, regression analyses will be used to detect predictors for failing on-road driving assessment.

Study description

Background summary

Parkinson*s disease (PD) is a complex neurodegenerative disease, with cognitive impairment being one of the most important non-motor symptoms. Cognitive decline impairs the execution of complex tasks in daily living, for example driving a car. Previous research showed that driving ability is diminished in PD patients. In the Netherlands, the Dutch driving licensing agency (Centraal Bureau Rijvaardigheidsbewijzen - CBR) takes care of the assessment of driving ability on-road. Although guidelines exist in Dutch legislation about the standard timing of this assessment, no screening instruments are available if patients should be referred to the CBR. Consequently, patients who are cognitively impaired, and would not pass the CBR assessment, may not be referred to the CBR, while patients who are still able to drive safely, with no or minor cognitive impairments, are referred because of the standardized

assessments over time. In this study we want to establish a clear and sensitive cut-off score on an established cognitive screening instrument, i.e. the Montreal Cognitive Assessment (MoCA), which will help physicians to decide when a patient should be referred to the CBR, or to prevent non-referrals and unnecessary referrals.

Study objective

The primary objective of this study is to establish a cut-off score on the MoCA, with a high, preferably 100%, sensitivity and reasonable specificity (>70%), in order to identify patients who will fail the CBR assessment, being unfit to drive. . If a 100% sensitivity with reasonable specificity (>70%) cannot be reached using only the MoCA score, clinical- and/or demographic variables will be added to the model to increase sensitivity/specificity. The secondary objective is to explore underlying factors determining which PD patients fail the on-road driving test.

Study design

This study is designed as an observational study of 45 early phase PD patients, all currently being active drivers.

Study burden and risks

All participants will attend the University Medical Center Groningen (UMCG) once for neuropsychological assessment, motor assessment and a driving simulator test. The duration of this session is approximately 3,5 - 4 hours, including a break of half an hour. Additional breaks will be set at the patient*s request. The on-road driving test will be scheduled within three months after the tests in the UMCG, at the participant*s local office of the CBR. The on-road driving test has a maximum duration of 60 minutes.
Possible benefits of participating in this study are the free assessment of driving ability and fitness tot drive. Participants who have failed the on-road driving test are advised to stop driving, however without a legal consequence for their driving license.
Participants may experience simulator sickness (similar to car sickness) during the driving simulator test. Participants are notified of this possibility beforehand and they will be monitored during the test. They will also be informed of their right to stop the test at any time. A general risk is that assessments (neuropsychological assessment and driving simulator assessment) can be too demanding for patients; however, neuropsychologists carrying out the assessments are experienced in testing vulnerable patients and will carefully check whether the assessments are too demanding, and will cease the assessments if necessary.

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

- Diagnosis Parkinson*s disease, as confirmed by a neurologist specialized in Parkinson*s Disease, by the UK-Brain Bank Criteria.
- Disease duration between 35-60 months, measured after time of diagnosis.
- Active driver
- Own a car or have access to a car
- Age 18 to 75
- Dutch speaking
- Willingness to cooperate and sign written informed consent

Exclusion criteria

- Suffering from severe motion sickness; motion sickness is a risk factor for simulator sickness.
- Use of category III medication, that may - according to current legislation - interfere with FTDr. The website www.rijveiligmetmedicijnen.nl will be used to check the classification of medication.
- Presence of premorbid pathology, i.e. experienced cerebral infarction or chronic depression, non-related to Parkinson*s disease.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-11-2021
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	29-09-2021
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	In afwachting
CCMO	NL76304.042.21