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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29145

Source
Nationaal Trial Register

Brief title
DUPARC-drive2

Health condition

Parkinson's disease

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

A cut-off score on the MoCA, that predicts failing an on-road driving test with high, preferably

100%, sensitivity and reasonable specificity (74%). Results of the MoCA and on-road driving test will be collected at approximately the same time (the on-road driving test will take place within 3 months after the visit to the UMCG).

Secondary outcome

The secondary objective is to gain insight in the underlying functions that can cause some PD patients to fail the on-road driving assessment. Secondary outcome measures will be taken into account are:
- driving simulator performance (UMCG visit), e.g. standard deviation of the lateral position, speed, percentage of lane crossing, reaction time to triggered events and number of violations;
- risk taking behaviour, using neuropsychological test results (UMCG visit) such as the Action Selection Task from the Institute for Road Safety Research (SWOV);
- cognitive functioning, using neuropsychological tests that assess functions that are important for fitness to drive (UMCG visit);
- motor functioning, using the Movement Disorders Society Unified Parkinson's Disease Rating Scale (UMCG visit).

Study description

Background summary

Rationale: Parkinson's disease (PD) is a complex neurodegenerative disease, with cognitive impairment being one of the most important non-motor symptoms. Cognitive decline can impair the execution of many complex tasks in daily living, for example driving a car. It is established that driving ability is diminished in PD patients and, in the Netherlands, at some point in the course of the disease patients need to have their driving ability assessed on-road by the Dutch driving licensing agency (Centraal Bureau Rijvaardigheidsbewijzen - CBR). Although basic guidelines exist in Dutch legislation about when this assessment should take place, these are open for interpretation and no clear cut-off on any test or screening instrument exists indicating when a physician should refer a patient to the CBR. In the proposed study we hope to establish a clear and sensitive cut-off score on an established cognitive screening, i.e. the Montreal Cognitive Assessment (MoCA), which will help physicians decide when a patient should be referred to the CBR.
Objective: The primary objective of this study is to establish a cut-off score on the MoCA, with which a high (preferably 100%) sensitivity can be reached to detect patients who fail the CBR assessment and are unfit to drive. The secondary objective is to explore underlying factors why some PD patients fail an on-road driving test.
Study design: This study is designed as an observational study of 45 early phase PD patients, all currently active drivers. Participation involves one visit to the UMCG, consisting of 1) a neuropsychological assessment, 2) a motor assessment, and 3) a driving simulator test, with a total duration of 3,5 – 4 hours, including a break of half an hour. Additional breaks can be taken at the participant's request. In addition, an on-road driving test will be scheduled on a

later date at the participant’s local office of the CBR, within 3 months after the participant's visit to the UMCG. The driving test and the visit to the UMCG will be considered as one timepoint (as we do not expect any (cognitive- or motor-) deterioration within these three month). The driving test has a maximum duration of 60 minutes.
Study population: 45 early phase PD patients, i.e. 3-5 years post onset, who are active drivers and are between and 74 years old. Patients will be recruited from the Dutch Parkinson Cohort (DUPARC; Boertien et al., 2020), or from the neurological practices in the northern area of the Netherlands.
Main endpoints: The primary endpoint will be finding a cut-off score on the MoCA that has high, preferably 100%, sensitivity and reasonable specificity (74%) in predicting failing the CBR on-road driving assessment.

Study objective

The MoCA can be used to predict failure on an on-road driving test.

Study design

Cross-sectional

Intervention

N/A

Contacts

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Eligibility criteria

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 fitness to drive.
- 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	45
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL9187
Other	METC UMCG : In progress

Study results

Summary results
N/A