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

Gepubliceerd: 17-12-2020 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29145

Bron
Nationaal Trial Register

Verkorte titel
DUPARC-drive2

Aandoening

Parkinson's disease

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Cross-sectional

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

University Medical Center Groningen
Hanna Slomp

0503614817

Wetenschappelijk

University Medical Center Groningen
Hanna Slomp

0503614817

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9187
Ander register	METC UMCG : In progress

Resultaten

Samenvatting resultaten
N/A