Dutch Parkinson, Cognition and Driving Ability study (DUPARC-drive): An explorative study on driving simulator performance in de novo Parkinson’s Disease patients

Gepubliceerd: 24-06-2020 Laatst bijgewerkt: 13-01-2025

De novo Parkinson's patients already present with declined driving ability at time of diagnosis, compared to age- and sex matched healthy controls.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20215

Bron
Nationaal Trial Register

Verkorte titel
DUPARC-drive

Aandoening

Parkinson's disease

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Driving simulator performance of de novo PD patients compared to HC, using the SDLP during Swing Drive part 1.

Toelichting onderzoek

Achtergrond van het onderzoek

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 activities, for example driving a car. It is established that driving ability is diminished in PD patients, in which a decline in cognitive functioning is an important factor. However, cognitive decline can also precede motor manifestations of PD by years, suggesting that recently diagnosed de novo PD patients might already be at risk for unsafe driving. The proposed study will be the first study to explore driving ability in de novo, treatment-naïve PD patients.
The primary objective of this study is to study whether driving ability may be affected in de novo, treatment naïve PD patients, by comparing their driving simulator performance to age- and sex-matched healthy controls (HC). The secondary objective is to explore neuropsychological- and motor variables that may correlate with driving simulator performance at time of diagnosis.
Study design: This study is designed as an explorative study of 30 de novo PD patients and 30 sex- and age matched healthy controls (HC), all currently active drivers. Patients and HC will undergo neuropsychological assessment and driving simulator assessment.
The primary endpoint will be driving simulator performance of de novo PD patients compared to HC, using the standard deviation of the lateral position (SDLP) during Swing Drive part 1 as primary variable. Secondary endpoints will be other driving simulator variables (e.g. speed, percentage of lane crossing, reaction time to triggered events and number of violations) and the identification of correlates between SDLP and potential predictors, i.e. neuropsychological test scores and motor scores.

Doel van het onderzoek

De novo Parkinson's patients already present with declined driving ability at time of diagnosis, compared to age- and sex matched healthy controls.

Onderzoeksopzet

Cross-sectional

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All subjects:
- Dutch speaking
- In possession of a driver’s license
- Active drivers, i.e., having driven at least 300 kilometres in the last year
- Age 18 to 75
- Willingness to cooperate and sign written informed consent

De novo PD subjects:
- Diagnosis Parkinson’s disease, as confirmed by a neurologist specialized in Parkinson’s Disease, by the UK-Brain Bank Criteria.
- Disease duration < 3 months, measured after time of diagnosis.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

All subjects:
- Suffering from severe motion sickness; motion sickness is a risk factor for simulator sickness.
- Use of category III medication.

De novo PD subjects:
- History of dopaminergic medication use.
- Presence of premorbid pathology, i.e. experienced cerebral infarction or chronic depression, non-related to Parkinson’s disease.

Healthy control subjects:
- Presence of psychiatric disorders, i.e. depression or psychosis.
- History of neurological disorders, which may interfere with cognitive functioning (e.g. recent concussion, previous subarachnoid or intracerebral haemorrhage, intracranial tumours, epilepsy, ischemic strokes).

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:	24-07-2020
Aantal proefpersonen:	60
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

Positief advies
Datum: 24-06-2020
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49421
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8727
CCMO	NL73666.042.20
OMON	NL-OMON49421

Resultaten

Samenvatting resultaten
N/A