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

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

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20215

Source
Nationaal Trial Register

Brief title
DUPARC-drive

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

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

Secondary outcome

Secondary outcome measures 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.

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 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.

Study objective

De novo Parkinson's patients already present with declined driving ability at time of

diagnosis, compared to age- and sex matched healthy controls.

Study design

Cross-sectional

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

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):	24-07-2020
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	24-06-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49421
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A