Validation of finger tapping in PD patients

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26165

Source
Nationaal Trial Register

Brief title
CHDR1953

Health condition

Parkinson's disease

Sponsors and support

Primary sponsor: CHDR
Source(s) of monetary or material Support: CHDR

Intervention

Outcome measures

Primary outcome

Pharmacodynamic endpoints
1. Alternate finger tapping task endpoints
2. Repetitive finger tapping task endpoints
3. MDS-UPDRS III total score and subscores

Secondary outcome

User experience and subjective burden of the touchscreen-based tapping and the goniometer tapping tasks.

Study description

Background summary

Prolonged dopamine (DA) replacement and DA agonist therapy for Parkinson's disease (PD) is associated with unwanted motor fluctuations. These motor fluctuations tend to occur when DA medication is wearing off, referred to as ON and OFF states. ON state is characterized by stable motor functioning at the medication's optimal efficacy level. OFF state is characterized by recurring parkinsonian symptoms.

PD severity is assessed by the Unified Parkinson's Disease Rating Scale (UPDRS) and its Movement Disorder Society (MDS-UPDRS)-revised version. Currently, the MDS-UPDRS is the 'gold standard' in clinical studies on PD. It is often used to monitor therapeutic efficacy by assessing motor function improvement in response to dopaminergic treatment or rate of progression of motor function decline over time. However, as motor symptom severity assessment occurs via observer ratings, the scale's applicability poses certain disadvantages. First, MDS-UPDRS assessment can be subject to varying inter-rater reliability. Second, patient visits and MDS-UPDRS' examinations are time consuming and costly. Lengthy assessments are not feasible when examining treatment effects of fast-acting dopaminergic agents. Third, clinician-based rating scales lack sensitivity to precisely monitor motor fluctuations throughout a day. Currently used patient reports and diaries can be subject to recall bias or faulty self-assessment. Taken together, there is a need for a shorter and more reliable tool to assess dopaminergic treatment effects.

Literature suggests that finger tapping tasks would be suitable for this purpose and would provide an additional pharmacodynamics measure, which is shorter in duration than the gold standard MDS-UPDRS part III. In this validation study, we chose a touchscreen based alternate finger tapping task and a goniometer task since these are likely able to provide sensitive data regarding tapping accuracy and speed and are not dependent on the strength by which the PD patients can press the screen. The current aim of the study is therefore, to assess whether the various finger tapping tasks are a sensitive measure in discriminating between ON/OFF states, is responsive to dopaminergic (i.e. levodopa/carbidopa) treatment and correlates with the MDS-UPDRS part III score.

Study objective

Primary Objectives
Assess whether the finger tapping task endpoints:
• Differentiate between ON and OFF states in PD patients

• Correlate with the MDS-UPDRS part III total score
• Differentiate between placebo and levodopa/carbidopa treatment
Secondary Objectives
• Evaluate inter- and intra-subject variability of each endpoint of the finger tapping tasks
• Evaluate user satisfaction of the AFT task and the goniometer

Study design

- Screening
- Two treatment periods of 2 days each (with overnight stay) with at least a 7-day washout period in-between.

Intervention

1-5 capsules levodopa/carbidopa 100/25 mg, over-encapsulated oral tablets or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Aged 20-85 years, inclusive at screening.
2. Clinical diagnosis (confirmed by a neurologist) of PD and classified by the investigator as Hoehn & Yahr stage I-III in the ON state.
3. Subject has self-described motor fluctuations and recognizable OFF periods.
4. Taking oral anti-Parkinson medication and willing to withhold medication overnight for study purposes.
5. Known to be levodopa responsive, either by current use or historical use of levodopa.
6. Willing and able to maintain stable doses and regimens for all medications, herbal

treatments and dietary supplements from the screening visit through the last study visit.
7. Negative urine tests for selected drugs of abuse. However, positive urine drug screen for Parkinson’s disease related medication is allowed at the discretion of the PI.
8. Willing and able to abstain from alcohol 24 hours prior to each CHDR visit. Negative alcohol breath test at screening and pre-dose.
9. Must be capable to communicate in the Dutch language.
10. Signed informed consent prior to any study-mandated procedure.

Exclusion criteria

1. History, signs or symptoms suggesting the diagnosis of secondary or atypical parkinsonism.
2. Previous intolerance, potentially relevant interaction of co-medication with or contraindication to levodopa and/or carbidopa.
3. Evidence of any active or chronic disease or condition that could interfere with, or for which the treatment of might interfere with, the conduct of the study, or that would pose an unacceptable risk to the subject in the opinion of the investigator (following a detailed medical history, physical examination, vital signs (systolic and diastolic blood pressure, pulse rate, body temperature) and 12-lead electrocardiogram (ECG)). Minor deviations from the normal range may be accepted, if judged by the Investigator to have no clinical relevance.
4. Clinically significant abnormalities, as judged by the investigator, in laboratory test results (including hepatic and renal panels, complete blood count, chemistry panel and urinalysis). In the case of uncertain or questionable results, tests performed during screening may be repeated before randomization to confirm eligibility or judged to be clinically irrelevant for healthy subjects.
5. Positive Hepatitis B surface antigen (HBsAg), Hepatitis C antibody (HCV Ab), or human immunodeficiency virus antibody (HIV Ab) at screening.
6. Last dosing in a previous investigational drug study within 3 months prior to first dosing of this study.
7. Any known factor, condition, or disease that might interfere with treatment compliance, study conduct or interpretation of the results such as drug or alcohol dependence or psychiatric disease.
8. Female patients who are pregnant, trying to become pregnant, or nursing (lactating) an infant.
9. Having a levodopa equivalent dose of the morning medication that exceeds 500 mg.

Study design

Design

Study type:	Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2020
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion

Date:	13-05-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49757
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8617
CCMO	NL73068.056.20
OMON	NL-OMON49757

Study results

Summary results
N.A.