Validation of finger tapping in PD patients

Gepubliceerd: 13-05-2020 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies	
Status	Werving gestopt	
Type aandoening	-	
Onderzoekstype	Interventie onderzoek	

Samenvatting

ID

NL-OMON26165

Bron Nationaal Trial Register

Verkorte titel CHDR1953

Aandoening

Parkinson's disease

Ondersteuning

Primaire sponsor: CHDR Overige ondersteuning: CHDR

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pharmacodynamic endpoints 1. Alternate finger tapping task endpoints

1 - Validation of finger tapping in PD patients 15-05-2025

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

- Screening

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Centre for Human Drug Research Geert Jan Groeneveld

+31 71 5246 400

Wetenschappelijk

Centre for Human Drug Research Geert Jan Groeneveld

+31 71 5246 400

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

 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.
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.

Onderzoeksopzet

Opzet

Туре:	Interventie onderzoek	
Onderzoeksmodel:	Cross-over	
Toewijzing:	Gerandomiseerd	
Blindering:	Dubbelblind	
Controle:	Placebo	

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	15-08-2020
Aantal proefpersonen:	20
Туре:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting N.A.

Ethische beoordeling

Positief advies	
Datum:	13-05-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49757 Bron: ToetsingOnline Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten N.A.