Quantification of Parkinson*s Disease motor symptoms using the PowerGlove

Published: 21-08-2014
Last updated: 21-04-2024

The main objective of this study is to evaluate whether the PowerGlove is a valid instrument that can be used for the assessment of hand motor symptoms in patients with Parkinson*s disease. Sensitivity, specificity, intra-examiner reliability and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON40878

Source
ToetsingOnline

Brief title
iDBS-PowerGlove

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease, PD

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Technologiestichting STW (onderdeel van NWO),Toegepast Wetenschappelijk Instituut voor Neuromodulatie (TWIN)

Intervention

Keyword: Motor symptoms, Parkinson's disease, PowerGlove, Quantification

Outcome measures

Primary outcome

The primary study parameters in this study are the sensitivity, specificity and reliability of the PowerGlove system in measuring the Parkinson symptoms rigidity, bradykinesia and tremor.

These are derived from the relations between:

- moment of force and range of motion generated in passive wrist flexion, measured by the PowerGlove system,
- speed and amplitude of hand and finger kinematics in different active hand movement tasks, measured by the PowerGlove system,
- frequency characteristics and amplitude of hand movement in rest, measured by the PowerGlove system,

and

- UPDRS scores for rigidity, bradykinesia and tremor, assessed by an experienced clinician (UPDRS part III, items 20-25)

in different points over time, ON- and OFF-medication, and executed by different experienced clinicians.

Secondary outcome

Secondary study parameters of interest are:

- EMG activity recorded during passive wrist flexion.

- Gender

- Age

- Disease duration

- Medication use

- Dominant left of right hand

- Body weight

- Body length

- Hand size

Study description

Background summary

Parkinson*s disease (PD) is an age-related neurodegenerative disorder. It is estimated that in 2030, the 10 most populated nations in the world will have between 8.7 and 9.3 million PD patients. Deep Brain Stimulation (DBS) of the subthalamic nucleus (STN), one of the nuclei of the Basal Ganglia, has proven to be an effective treatment of the various motor symptoms and reduces medication needs. The goal of the iDBS-project is to automatically estimate the clinical condition of the PD patient and use this information to automatically control the stimulation parameters. Clinically, motor symptoms of a PD patient prior, during and after DBS implantation are scored during a standard neurological examination using parts of the Unified Parkinson*s Disease Rating Scale (UPDRS), estimating rigidity, bradykinesia, and tremor.
However, the assessment often varies per physician and highly depends on experience. The subjective nature makes it hard to interpret the UPDRS correctly and the current clinical exam may be too abbreviated to detect small changes. Recently, the University of Twente developed a PowerGlove that consists of miniature inertial (accelerometers and gyroscopes) and magnetic sensors on each finger segment and the back of the hand that enable accurate and ambulant measurement of hand and finger movements. Application of the

PowerGlove before, during and after DBS surgery might enable more accurate measure of hand motor function and objective quantification of the Parkinson*s disease motor symptoms.

Study objective

The main objective of this study is to evaluate whether the PowerGlove is a valid instrument that can be used for the assessment of hand motor symptoms in patients with Parkinson*s disease. Sensitivity, specificity, intra-examiner reliability and inter-examiner reliability will be tested.

Study design

In this observational study, measurements with PowerGlove system * consisting of the PowerGlove, force sensor, and EMG measurement setup * will be performed to examine the PD motor symptoms during a patient*s standard clinical examination. The patient will be admitted to the hospital one day prior to the clinical examination for withdrawal from medication. The next morning the patient will be in OFF state and a Parkinson nurse will do the screening of motor symptoms using, amongst others, the UPDRS. Next, the patient will get PD medication and the patient will be screened a one hour later in medication ON state. During both these clinical examinations, the PowerGlove system will also be used to measure rigidity, bradykinesia and tremor using the same simple hand movement tests as are used in the UPDRS.
The first measurement with the PowerGlove will consist of three sessions to test intra-examiner and inter-examiner reliability and will take around 30 minutes. The second measurement will only consist of a single session and will take around 15 minutes.

Study burden and risks

The burden and risks associated with participation are minimal. Because the measurement is scheduled together with the patient*s standard clinical examination before DBS, there are no extra travel burden or costs involved. The measurement is not invasive, the PowerGlove is comfortable to wear and for the measurement only six simple hand movement tasks have to be performed by the patient. The whole study will take approximately 45 minutes extra on top of the standard clinical examination. The greatest burden for the patient will be that he will be withdrawn from medication for 30 minutes longer than usual during the testing in OFF phase.
The patient has no direct benefit from this study, but an easy-to-use instrument that can measure PD motor symptoms objectively can benefit the patient group by making the examination of motor symptoms simple and accurate. This way, deterioration of symptoms over time can be identified in a better way. The same is true for the improvement of motor functions by medication or DBS. This will benefit the whole patient group and can, in the future, benefit

the participating patient as well.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- The patient has had Parkinson's symptoms for more than five years.
- The patient has a good response to dopaminergic medication.
- The patient is selected to undergo preoperative screening for Parkinson DBS surgery in the Academic Medical Center, Amsterdam.
- The patient is able to communicate adequately in Dutch or English.
- The patient is between the age of 18 and 80.

Exclusion criteria

- The patient has a medical (or other) history other than Parkinson's disease which restricts hand movement (e.g. a complicated wrist fracture of severe arthritis).
- Inability to correctly place the PowerGlove on the patient's hand or to correctly perform the necessary calibration.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2014
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO

Date:	21-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL48811.018.14