The assessment of the quality of movement control in patients with Parkinson*s disease receiving deep brain stimulation.

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The design of an ambulant system that is capable of long-term estimation of the right UPDRS-levels for tremor, bradykinesia, and akinesia in patients with Parkinson*s disease receiving deep brain stimulation in the subthalamic nucleus using a...

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

Summary

ID

NL-OMON30995

Source
ToetsingOnline

Brief title
Assessing movement control in Parkinson*s disease.

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Deep brain stimulation (DBS), Kinematic sensor, Movement control, Parkinson's disease

Outcome measures

Primary outcome

Parameters (obtained from the inertial sensors) relating to the UPDRS-scores

for tremor, bradykinesia, and akinesia during three conditions are compared.

These conditions are stimulator on with normal settings, stimulator on with

altered settings, and stimulator off.

The correlations of these parameters to the UPDRS-scores of tremor,

bradykinesia, and akinesia is also assessed.

Secondary outcome

not applicable

Study description

Background summary

Deep brain stimulation is an effective method to suppress symptoms relating to Parkinson*s disease. However, improvements are always possible. To make deep brain stimulation even more effective, it is necessary to adjust the settings of the stimulator in the most optimal way. Nowadays, the deep brain stimulator is adjusted subjectively by the specialist based on observations over short periods.
During this research, the possibilities for developing an objective ambulant system, which is capable of quantifying movement disturbances over long-term, are assessed. Eventually, the system should be able to quantify tremor, bradykinsia, and akinesia in such a way that different settings of the deep brain stimulator can be discriminated. In this way, the deep brain stimulator can be adjusted optimally, making the treatment more effective.

Study objective

The design of an ambulant system that is capable of long-term estimation of the right UPDRS-levels for tremor, bradykinesia, and akinesia in patients with Parkinson*s disease receiving deep brain stimulation in the subthalamic nucleus using a minimal number of kinematic sensors. The system should be sensitive enough to detect differences in UPDRS-levels at different settings of the stimulator.

Study design

Observational, non-invasive research.

Study burden and risks

The extent of the burden is a measurement taking maximally one and a half hour, performed at the *Medisch Spectrum Twente*. During the measurements, five inertial sensors will be attached to the body using dermatologic tested tape on the sternum, the wrist and the thigh of the most affected side, and both shanks. In addition, the stimulator will be turned off and the settings of the stimulator will be altered, both for a maximal period of 20 minutes. During the measurements, the subject is asked to perform some small movement tasks. A large part of these tasks is part of the UPDRS-test. This test and the turning off and change of settings of the stimulator are also performed during regular visits to the specialist.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Parkinson patients having a deep brain stimulator in the subthalamic nucleus
- Patients experiencing a good clinical result from DBS
- Patients having no major fluctuations in symptoms due to medication
- Patients being in good physical condition
- Patients responding within 5 minutes to changes in the stimulator settings

Exclusion criteria

- Patients not being able to fully cooperate with the experiments
- Patients suffering from dementia
- Patients suffering from severe dyskinesia

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL18703.044.07