Comparative study of experimentally observed effects of DBS in STN or GPi in Parkinon*s patients for different stimulation amplitude-frequency combinations.

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

Summary

ID

NL-OMON31600

Source
ToetsingOnline

Brief title
Relationship of Parkinson symptoms with DBS settings in STN and GPi.

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, globus pallidus, Parkinson, subthalamic nucleus

Outcome measures

Primary outcome

During the study the following experiments will be conducted:

akinesia: reactiontime

bradykinesia: time of movement

rigidity: momentum on the elbow and knee joint during

passive movement

tremor: amplitude and frequency

muscle contractions: amplitude, degree of occurence and correlation with

stimulationsignal

dysarthria: amplitude, fluency and frequency

These parameters will be measured in total at sixteen different stimulator

settings namely; three amplitude settings for five different frequency settings

(15 in total) and one stimulator off condition. This research has been split up

into three segments per group to minimize the stress upon one patient. This

means that one patient undergoes six different stimulator settings, see

protocol pages 10 and 11.

Eventually the degree of influence of, and the relationship between, the

different settings concerning the surpression of the different Parkinsonian

symptoms will be analyzed.

Secondary outcome

not applicable.

Study description

Background summary

Deep brain stimulation (DBS) is widely used as an effective method to reduce the utterance of Parkinson*s disease (PD) symptoms. However, the principle mechanism(s) of action are still poorly understood. To be able to increase the effectiveness of DBS for PD patients it is necessary to increase insight in the mechanisms of action of DBS by PD patients. By an increase in the insight into this mechanism of action it becomes possible to adjust the stimulator settings to an optimal state for PD patients in a shortened period of time in an objective manner. For now the stimulator settings are determined in a subjective manner by the specialist.

Study objective

The aim of this study is to determine objectively and quantitatively the relationship between different stimulation settings, in different nuclei (the subthalamic nucleus (STN) and the internal segment of the globus pallidus (GPi)) and the degree of utterance of PD symptoms.

Study design

Observational, non-invasive study, three way mixed design.

Study burden and risks

During this study the settings of the DBS stimulator will be changed six times for short periods of time. One of the settings is that the stimulator is switched off.
During these periods the following measurements will take place: reactiontime, time of movement, rigidity (by determining the momentum upon the elbow and knee joint during passive movement), tremor (by inertial sensors), involuntary

muscle contractions (by EMG) and dysarthria (by soundrecordings of a read out text). In addition the patient will be asked some disease related questions.

There are no or negligible risks for the patient concerning this study. During this study the stimulator settings will be changed for a short period of time, from which one setting is with the stimulator switched off. Changing the stimulator settings, however, also occurs during regular visits. At the end of the experiments the initial settings of the patients stimulator will be restored.

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 receiving DBS in the STN or GPi

- Patients underwent surgery at least three month ago
- Patients experiencing good clinical results from DBS
- Patients do not experience major fluctuations in symptoms due to medication
- Patients are in good physical condition
- Patients responding within 5 minutes to changes in the stimulator settings

Exclusion criteria

- Patients who cannot fully cooperate during 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):	01-11-2007
Enrollment:	128
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	NL20294.044.07