Investigation of the somatotopic organization of the subthalamic nucleus in Parkinson's patients with deep brain stimulation; movement measurements on Parkinson*s Disease patients for different deep brain stimulation settings.

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

Summary

ID

NL-OMON31328

Source
ToetsingOnline

Brief title
Somatotopic organization of the subthalamic nucleus

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), Parkinson's Disease, Somatotopic organization, Subthalamic nucleus (STN)

Outcome measures

Primary outcome

The study is designed to measure tremor, bradykinesia/akinesia and speech

dificiencies in Parkinson's disease. These factors can than be related to the

position of the electrode which is determined from preoperative MRI scans or

post-operative CT scans.

Secondary outcome

n.a.

Study description

Background summary

Deep brain stimulation (DBS) is a widely used method for the elevation of the symptoms of Parkinson Disease. The functional mechanisms of the study are however not completely known yet. There is also only little known about influence of the parameter settings in relation to the position of the electrode in the subthalamic nucleus (STN) on Parkinson's disease. In this study the influence of the stimulation of specific areas in the STN is determined. We hope to gain more insight in the functional mechanisms of DBS in Parkinson patients, in order to increase the effectiveness of the therapy.

Study objective

The aim of the study is to gain insight on the somatotopy of the subthalamic

nucleus. The relation between the postion o fthe electrode in the STN, the parameter settings of the stimulator and the effectiveness of the stimulation on Parkinson's disease is determined. The experiments are performed using inertial sensors on different body parts, arms and legs. The effect of deep brain stimulation on different parts of the body is examined. The position of the electrode is determined from available scans (MRI / CT). The experiments are than used to relate the position of the electrode to the effectiveness of the stimulation and the parameter settings.

Study design

Patient experiments are performed, using inertial sensors and EMG measurements on arms and legs, to measure the effectiveness of the stimulation under different stimulator settings.
In this study a group of Parkinson patients with an STN stimulator is asked to participate. Four different settings of the stimulator are used, in order to determine the influence of the stimulator on the symptoms of Parkinson disease. The influence is measured separately for arms and legs and left and right side, whereby the patients is asked to perform 3 simple movement tasks. All patients will perform the same experiments. The effectiveness will be determined using the tremor, bradykinesia/akinesia and speech difficiencies.

Intervention

The intervention of this research project is based on influencing the stimulator. The stimulator is adjusted to 4 different settings, of which 3 are different than the original setting of the stimulator. The 3 different settings comprise of: 1.) lowering the amplitude until tremor starts again, 2.) switching off the stimulator and 3.) changing the stimulated electrode contact and rising the amplitude until tremor has disappeared again.

Study burden and risks

Patients participating in the study will be asked to switch off the stimulator, or change the parameter settings of the stimulator. This will have an effect on the functioning of the stimulator. Patients may experience worsening of symptoms during the measurement with the changed parameter settings. The participants will need to spend a maximum of one and a half hours to complete the whole study. After the experiments the stimulator settings are returned to their original settings, so no permanent change in Parkinson symptoms is expected. The participants will not directly benefit from the study, but the study might help future patients to benefit more from their stimulator and to find the optimal target for stimulation and the optimal stimulation settings.

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

Patient suffers from Parkinson's disease
Patient has received bilateral DBS in the STN
Patient underwent surgery at least three month ago
Patient experiences a good clinical result from DBS
Patient has no major fluctuations in symptoms due to medication
Patient is in good physical condition
Patient responds within 5 minutes to changes in the stimulator settings

Exclusion criteria

Patient cannot fully cooperate with the experiments

Patient suffers from dementia
Patient suffers from severe dyskinesia/akinesia

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	15
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	NL18696.044.07