Randomised multicentre trial comparing bilateral subthalamic nucleus DBS and bilateral globus pallidus internus DBS for advanced Parkinson*s disease

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We hypothesize that bilateral globus pallidus internus (GPi) DBS produces greater functional improvement in PD than bilateral STN DBS because of a lower rate of complications.

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

Summary

ID

NL-OMON30282

Source
ToetsingOnline

Brief title
N-STAPS

Condition

- Movement disorders (incl parkinsonism)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Prinses Beatrix Fonds

Intervention

Keyword: Deep Brain Stimulation, Globus Pallidus, Parkinson's disease, Subthalamic Nucleus

Outcome measures

Primary outcome

Baseline and outcome measurements at 12 months will be done in standardized off and on phases. The primary outcome measures are the Neuropsychiatric Inventory (cognition, mood, and behavior) and the off-on phase weighted AMC Linear Disability Scale (functional improvement).

Secondary outcome

Secondary outcome consists of symptom scales, activities of daily living scales, a quality of life questionnaire, adverse effects, and medication use. Additionally, patients will undergo extensive neuropsychological assessment.

Study description

Background summary

Patients with advanced Parkinson*s disease (PD) and long-term pharmacologic treatment often have response fluctuations and involuntary movements (dyskinesias). Frequently they cycle between episodes with Parkinsonism associated with severe disability (*off* phase) and episodes with good mobility (*on* phase), usually with dyskinesias. Continuous bilateral subthalamic nucleus (STN) deep brain stimulation (DBS) is an effective surgical treatment for patients with advanced PD who have severe limitations in functioning despite optimal pharmacologic treatment. Recently however, the concerns about STN DBS and adverse effects are increasing, especially for the cognitive, mood, and behavioral features.

Study objective

We hypothesize that bilateral globus pallidus internus (GPi) DBS produces greater functional improvement in PD than bilateral STN DBS because of a lower

rate of complications.

Study design

The study will be a randomized, multi-center, double-blind trial comparing continuous bilateral GPi DBS with bilateral STN DBS in advanced PD.

Intervention

A neurosurgical procedure using stereotactic techniques will be employed for implantation of two electrodes with the functional contact at both subthalamic nuclei or both globus pallidus. The electrodes will be connected to an implantable pulse generator under general anesthesia. Patients will regularly visit a neurologist at the outpatient clinic to adjust stimulation parameters and PD medication while assessing the interaction between both treatments.

Study burden and risks

At baseline and 12 months follow-up, patients will be assessed in standardized off and on phases, which include withholding PD medication for 12 h and a hospital visit (3 h). Patients will complete a diary for three days. Additionally, an extensive neuropsychological evaluation in the on phase will be performed (3 h). If the study shows that bilateral DBS of the GPi produces greater functional improvement than bilateral STN DBS, then this will have a major impact on the current practice.

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

Inclusion criteria are idiopathic Parkinson's disease and * despite optimal pharmacological treatment * at least one of the following symptoms: severe response fluctuations, dyskinesias, painful dystonias, or bradykinesia.

Exclusion criteria

Exclusion criteria are: age below 18 years, previous functional stereotactic neurosurgery, Hoehn and Yahr stage 5 at the best moment during the day, a MATTIS dementia rating scale score of 120 or less, current psychosis or depression, and contraindications for stereotactic neurosurgery such as a physical disorder making surgery hazardous (severe hypertension, blood coagulation disorder, severe dysphagia, or dysarthria).

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2007
Enrollment:	128
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

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	NL11196.018.06