Randomized double-blind multicenter trial comparing bilateral subthalamic nucleus Deep Brain Stimulation (DBS) and bilateral globus pallidus DBS for advanced Parkinson’s disease.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23721

Source
NTR

Brief title
N-STAPS

Health condition

Advanced Parkinson's disease

Sponsors and support

Primary sponsor: Academic Medical Center - University of Amsterdam
Source(s) of monetary or material Support: Prinses Beatrix Fonds (WAR05-0203)

Intervention

Outcome measures

Primary outcome

The primary outcome measures are the number of patients with significant cognitive, mood, and behavioral adverse effects and the off-on phase weighted AMC Linear Disability Scale (functional improvement).
Significant cognitive, mood, and behavioral adverse effects are defined as worsening on three or more cognitive tests (based on the reliable change index), or the loss of professional activity/work/job, or the loss of an important relationship (e.g. marriage), or psychosis/depression/anxiety for a period of 3 months or longer.
Outcome measurements will be performed at baseline and 12 months after surgery.

Secondary outcome

Secondary outcome consists of symptom scales (UPDRS motor, CDRS), activities of daily living scales (ALDS and UPDRS ADL), a quality of life questionnaire (PDQL), adverse effects, and medication use. Additionally, patients will undergo extensive neuropsychological and standardized psychiatric assessment.

Study description

Background summary

Patients with advanced Parkinson’s disease (PD) and long-term pharmacologic treatment often have response fluctuations and 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.
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.
The study will be a randomized, multicenter, double-blind trial comparing continuous bilateral GPi DBS with bilateral STN DBS in advanced PD. We will enroll 128 patients with advanced PD who have—despite optimal pharmacological treatment—at least one of the following symptoms: severe response fluctuations, dyskinesias, painful dystonias, or bradykinesia. Patients will be randomly assigned to bilateral GPi DBS or bilateral STN DBS. Baseline and outcome measurements at 12 months will be done in standardized off and on phases. The primary outcome measures are the number of patients with significant cognitive, mood, and behavioral adverse effects and the off-on phase weighted AMC Linear Disability Scale (functional improvement). 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 an extensive neuropsychological and a standardized psychiatric assessment. Five centers in the Netherlands performing functional stereotactic neurosurgery will participate.

Study objective

Assuming that the effects on Parkinson's disease symptoms and dyskinesias, and the rates of procedure-related and device-related complications are almost equal, then continuous bilateral GPi DBS may produce greater functional improvement than bilateral STN stimulation in Parkinson's disease, because the latter is associated with long-term cognitive, mood, and behavioral problems.

Intervention

Stereotactic bilateral implantation of DBS electrodes in the globus pallidus internus or the nucleus subthalamicus.

Contacts

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Eligibility criteria

Inclusion criteria

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

1. Age below 18 years;
2. Previous functional stereotactic neurosurgery;
3. Hoehn and Yahr stage 5 at the best moment during the day;
4. A Mattis dementia rating scale score of less than 120;
5. Psychosis, and contraindications for stereotactic neurosurgery such as a physical disorder making surgery hazardous (severe hypertension, blood coagulation disorder, severe dysphagia, or dysphasia).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-12-2006
Application type:	First submission

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
NTR-new	NL814
NTR-old	NTR827
Other	: WAR05-0203
ISRCTN	ISRCTN85542074

Study results

Summary results
N/A