

Randomised double-blind multicentre trial comparing bilateral subthalamic nucleus deep brain stimulation and bilateral globus pallidus deep brain stimulation for advanced Parkinson's disease

Submission date 16/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/07/2016	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Patients with advanced Parkinson's disease often do not respond well to medication. When this is the case, deep brain stimulation (DBS) is a treatment option to improve stiffness, shaking and slowness. DBS is a type of surgery in which two electrodes are placed deep in the brain: one on each side of the brain. These electrodes transmit a current that relieves symptoms. This can be done in a brain area called the subthalamic nucleus (STN) or in an area called the globus pallidus (GPi). This study compares the effects of DBS of the STN with DBS of the GPi.

Who can participate?

Patients with Parkinson's disease suffering from uncontrollable involuntary movements, pain, or severe slowness can participate.

What does the study involve?

Patients are randomly allocated to receive DBS of either the STN or the GPi. Afterwards, they are followed extensively, for up to 5 years, to monitor the effects on motor symptoms, mental status, and behavior.

What are the possible benefits and risks of participating?

Both STN DBS and GPi DBS are already established treatment options for advanced PD. Risks of surgery include hemorrhage (bleeding), infection and malfunctioning of the equipment.

Where is the study run from?

The study is run from the Academic Medical Center, Amsterdam, The Netherlands. Four other centers in the Netherlands have participated

When is the study starting and how long is it expected to run for?

Patient recruitment ran from January 2007 until May 2012

Who is funding the study?

Stichting Internationaal Parkinson Fonds, Prinses Beatrix Fonds, and Parkinson Vereniging (Netherlands)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

WAR05-0203

Study information

Scientific Title

Randomised double-blind multicentre trial comparing bilateral subthalamic nucleus deep brain stimulation and bilateral globus pallidus deep brain stimulation for advanced Parkinson's disease

Acronym

N-STAPS

Study objectives

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 Globus Pallidus Deep Brain Stimulation (GPi DBS) may produce greater functional improvement than bilateral SubThalamic Nucleus (STN) stimulation in Parkinson's disease, because the latter is associated with long-term cognitive, mood, and behavioural problems.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medisch Ethische Commissie AMC, 17/05/2006, ref: MEC 06/084 # 07.17.0069. Last amendment approval received on 11/01/2007.

Study design

Randomised controlled parallel-group double-blinded multicentre trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Parkinson's disease

Interventions

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

Intervention Type

Procedure/Surgery

Primary outcome measure

The number of patients with significant cognitive, mood, and behavioural adverse effects and the off-on phase weighted Academic Medical Centre (AMC) Linear Disability Scale (functional improvement).

Significant cognitive, mood, and behavioural 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 three months or longer.

Outcome measurements will be performed at baseline and 12 months after surgery.

Secondary outcome measures

Secondary outcome consists of:

1. Symptom scales (Unified Parkinson's Disease Rating Scale [UPDRS] motor, Clinical Dyskinesia Rating Scale [CDRS])
2. Activities of daily living scales (ADLS) and UPDRS Activity of Daily Living (ADL) scale
3. A quality of life questionnaire (Parkinsons Disease Quality of Life [PDQL])
4. Adverse effects
5. Medication use

Additionally, patients will undergo extensive neuropsychological and standardised psychiatric assessment.

Overall study start date

01/01/2007

Completion date

01/07/2012

Eligibility

Key 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

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

128

Key exclusion criteria

1. Age below 18 years
2. Previous functional stereotactic neurosurgery
3. Hoehn and Yahr stage five 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)

Date of first enrolment

01/01/2007

Date of final enrolment

01/05/2012

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

Sponsor details

PO Box 22660

Amsterdam

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1100 DD

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl/>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Research organisation

Funder Name

Prinses Beatrix Fonds (Netherlands)

Funder Name

Internationaal Parkinson Fonds (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2013		Yes	No
Results article	results	23/02/2016		Yes	No