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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

Registration date
16/01/2007

Overall study status
Completed

Last Edited
04/07/2016

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Additional identifiers

Protocol serial number
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.

Primary study design
Interventional

Study design
Randomised controlled parallel-group double-blinded multicentre trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

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