The GALAXY study: General Anesthesia versus Local Anesthesia in StereotaXY for Deep Brain Stimulation in Parkinson*s disease, a randomized controlled trial.

Published: 17-02-2016
Last updated: 18-07-2024

Primary Objective: To optimize the current DBS-treatment of advanced PD. For the primary objective the following research questions will be answered: By performing STN DBS under general anesthesia, will there be a significant reduction in cognitive...

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

Summary

ID

NL-OMON47557

Source
ToetsingOnline

Brief title
GALAXY (General Anesthesia versus Local Anesthesia in stereotaXY)

Condition

- Movement disorders (incl parkinsonism)
- Nervous system, skull and spine therapeutic procedures

Synonym
Parkinson's disease, primary parkinsonism, shaking palsy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,is aangevraagd

Intervention

Keyword: Deep brain stimulation, General anesthesia, Parkinson's disease

Outcome measures

Primary outcome

The primary outcome measures is the number of patients with significant postoperative cognitive, mood and behavioral adverse effects indicated by a stringent composite score of >1 within 6 months after STN DBS.

Secondary outcome

Secondary outcome measures are:

- Motor score: MDS-UPDRS

- Clinical Dyskinesia Rating Scale (CDRS)

- Daily functioning: MDS-UPDRS (activities of daily living section), Functional health status (ALDS)

- Quality of life: PDQ-39

- Treatment satisfaction (See F-vragenlijsten, Treatment satisfaction)

- Burden of therapy (See F-vragenlijsten, Burden of therapy)

- Surgery time, duration of hospital admittance

- PD- medication changes

- Other adverse effects and complications than those registered in the composite score

- Other psychiatric effects and complications than those registered in the

composite score, measured with: Young Mania Rating Scale, Columbia Suicide

Severity Rating Scale, Hamilton Depression Rating Scale, Hamilton Anxiety

Rating Scale, Starkstein Apathy Rating Scale.

Study description

Background summary

Continuous deep brain stimulation (DBS) of the subthalamic nucleus (STN) is an effective surgical treatment for patients with advanced Parkinson*s disease (PD) who have severe limitations in functioning despite optimal pharmacologic treatment. Currently the standard DBS procedure is performed under local anesthesia. Unfortunately procedure is very burdensome for patients. Due to advances in modern imaging techniques, it is now possible to visualize the target nuclei for DBS in the brain directly. Surgery for DBS could therefore now be performed under general anesthesia. To determine if DBS under general anesthesia produces less cognitive, affective and behavioural side effects compared to local anesthesia, a comperative study is warranted.

Study objective

Primary Objective: To optimize the current DBS-treatment of advanced PD. For the primary objective the following research questions will be answered: By performing STN DBS under general anesthesia, will there be a significant reduction in cognitive, mood and behavioral adverse effects when compared to STN DBS under local anesthesia?

Secondary Objectives: Secondary objectives are to compare motor symptoms (incl. UPDRS), health related functioning, adverse effects and complications, psychiatric adverse effects, surgery time, quality of life, patient satisfaction on the outcome of treatment, and patient evaluation of the burden of therapy.

Study design

The study will be a single centre prospective randomized open blindend end-point (PROBE) trial comparing STN DBS under general versus local anesthesia. A total of 110 patients with advanced Parkinson's disease who are candidates for deep brain stimulation will be randomized.

Three and five years after the placement of deep brain electrodes, during a standard of care appointment, the extent of sustained improvement in symptoms

of Parkinson's disesae is measured next to a number of daily functioning and psychiatric questionnaires are taken.

Intervention

Patients will be randomized to DBS under general anesthesia or DBS under local anesthesia. As is standard procedure, 2 electrodes will be implanted in the brain connected to an implanted pulse generator, which will be placed subcutaneously in the subclavian area.

Study burden and risks

If DBS surgery is perfomed under general anesthesia, this would significantly lower the risk of experiencing side effects associated with local anesthesia. Local anesthesia at present is very burdensome for all patients and holds back some who are actually good candidates for the procedure. DBS under general anesthesia will have a shorter procedure length. Additionally it will lead to less postoperative confusion which now adds to the operative burden and this will shorten hospital admittance as secondary benefit.

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

- Age > 18 years;
- Idiopathic PD with bradykinesia and at least two of the following signs; resting tremor, rigidity, and asymmetry;
- Despite optimal pharmacological treatment, at least one of the following symptoms: severe response fluctuations, dyskinesias, painful dystonia or bradykinesia;
- A life expectancy of at least two years.

Exclusion criteria

- Legally incompetent adults
- Previous PD-neurosurgery (e.g., DBS, pallidotomy, thalamotomy);
- Contraindications for DBS surgery, such as a physical disorder making surgery hazardous;
- Hoehn and Yahr stage 5 at the best moment during the day;
- Psychosis;
- Current depression;
- No written informed consent;

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2016
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	17-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-12-2019
Application type:	Amendment
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

ID: 21184
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL53375.018.15