Effects of bilateral subthalamic nucleus deep brain stimulation on plasma triglycerides and glucose metabolism in patients with advanced Parkinson*s disease.

Published: 12-11-2008 Last updated: 07-05-2024

Does bilateral deep brain stimulation of the subthalamic nucleus in patients with Parkinson's disease influence plasma triglycerides and glucose metabolism?

Ethical review	Approved WMO
Status	Pending
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON31844

Source ToetsingOnline

Brief title Effects of subthalamic nucleus stimulation on metabolism

Condition

- Hypothalamus and pituitary gland disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Movement disorders (incl parkinsonism)

Synonym

Lipids and glucose metabolism in patients with Parkinson disease

Research involving

Human

1 - Effects of bilateral subthalamic nucleus deep brain stimulation on plasma trigly ... 7-05-2025

Sponsors and support

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

Intervention

Keyword: Deep brain stimulation, Glucose metabolism, Parkinson's disease, Triglycerides

Outcome measures

Primary outcome

Evaluation of the effect of stimulation on the subthalamic nucleus on plasma

triglycerides and glucose metabolism.

Secondary outcome

NA

Study description

Background summary

Observations showed involvement of the hypothalamus in glucose-, and triglycerides metabolism. Patients with a deep brain stimulator might also have a change in the glucose metabolism and plasma triglycerides due to the deep brain stimulator. With this study we would like to get more insight in the influence of the metabolism of patients with a deep brain stimulator of the subthalamic nucleus.

Study objective

Does bilateral deep brain stimulation of the subthalamic nucleus in patients with Parkinson's disease influence plasma triglycerides and glucose metabolism?

Study design

An observational cohort study with inclusion of 10 patients, visiting 5 times.

Study burden and risks

Labelled glucose behaves in vivo as unlabeled glucose and therefore has no side

2 - Effects of bilateral subthalamic nucleus deep brain stimulation on plasma trigly ... 7-05-2025

effects.

Labelled water may cause some dizziness, for that reason patients consume this in 5 equal portions with an interval of 30 minutes.

During the 2 visits of evaluation 250 ml of blood will be withdrawn per visit.

At the insertion of the venous cannula, a hematoma may occuur.

Contacts

Public Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Amsterdam Nederland **Scientific** Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Amsterdam Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Patients with idiopathic Parkinson's disease, bilateral subthalamic nucleus deep brain stimulation, and a documented effect of bilateral subthalamic nucleus deep brain stimulation on parkinsonism *measured with the Unified Parkinson*s disease Rating Scale (UPDRS) motor section*equal or more than 75% of the difference between the preoperative provoked OFF and ON phases.

3 - Effects of bilateral subthalamic nucleus deep brain stimulation on plasma trigly ... 7-05-2025

Exclusion criteria

Age less than 18 years, other functional stereotactic neurosurgical interventions (e.g. pallidotomy), psychosis, depression, alcoholism, dyslipidemia (primary or secondary form), use of lipid lowering drugs, unstable weight, presence of type II diabetes mellitus, former history of diabetes gravidarum, first line familial preponderance of type II diabetes mellitus, active smoking, renal insufficiency (creatinine > 150 umol/L, creatinine clearance <60 ml/min) or elevated liver enzymes (2x upper limit).

Study design

Design

Study type:	Observational invasive	
Intervention model:	Parallel	
Allocation:	Randomized controlled trial	
Masking:	Single blinded (masking used)	
Control:	Active	
Primary purpose:	Basic science	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2008
Enrollment:	10
Туре:	Anticipated

Ethics review

Approved WMO Application type: Review commission:

First submission 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 CCMO **ID** NL22171.018.08