Evaluation of the effect of deep brain stimulation on the dopamine household in Parkinson*s disease.

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The present study proposal could be able to provide an answer to the following questions:1) what is the effect of the oral administration of levodopa on the synaptic dopamine concentration in end-stage Parkinson*s disease?2) how does microlesioning...

Ethical review	Approved WMO
Status	Pending
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational invasive

Summary

ID

NL-OMON32074

Source
ToetsingOnline

Brief title
PET study of the effect of DBS in Parkinson's disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Deep brain stimulation, Dopamine, Parkinson's disease, Positron emission tomography

Outcome measures

Primary outcome

The levodopa-induced change in synaptic dopamine concentration after versus

before DBS.

Secondary outcome

The baseline dopamine receptor binding before and after DBS.

Study description

Background summary

The (sub)acute effects on the dopamine household of deep brain stimulation as a treatment modality in moderate to advanced Parkinson*s disease is still incompletely understood.

Study objective

The present study proposal could be able to provide an answer to the following questions:

1) what is the effect of the oral administration of levodopa on the synaptic dopamine concentration in end-stage Parkinson*s disease?
2) how does microlesioning the STN/GPi influence the baseline dopamine receptor binding?
3) how does microlesioning the STN/GPi influence the levodopa-induced change in synaptic dopamine concentration?
4) what is the relationship between the motor behaviour in general and the occurrence of wearing-off fluctuations and dyskinesias in particular after the STN procedure and the measured levodopa-induced changes in synaptic dopamine concentration levels?

Study design

A longitudinal study with two imaging assessment points namely before and after

scheduled deep brain stimulation.

Study burden and risks

The burden of the present study lies in the amount of time spent during the imaging session (two times 3 hours), the clinical assessments before and after deep brain stimulation (dyskinesia scaling), the associated radiation risks related to positron emission tomography scanning (6 mSv) and the fact of being sobre both concerning food and dopaminergic medication up to 12 hours before scanning.

There is no direct benefit related to the study apart from an even more complete assessment of the patient.

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

Patients with end-stage Parkinson*s disease, being scheduled for deep brain stimulation.

Exclusion criteria

None.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL21380.042.08