The emotional response in Parkinson`s disease before and after bilateral STN stimulation

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To gain knowledge about the etiology of emotional changes after bilateral STN stimulation. And also to find out that the research design, where neuropsychological and psysiological aspects are combined, is useful in studying outcomes of STN...

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

Summary

ID

NL-OMON30351

Source
ToetsingOnline

Brief title
Emotional respons and STN

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson movementdisorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Emotional response Parkinson STN

Outcome measures

Primary outcome

auditive startle reflex (latency, duration and peak of the amplitude EMG

activity per muscle)

tactile startle reflex (latency, duration and peak of the amplitude EMG

activity per muscle)

Psychogalvanic respons (difference between the minimum and maximum activity in

a period of four seconds after stimulus onset)

Affective reports on arousal and valence (Self Assessment Manikin)

Secondary outcome

General cognitive functioning (Mattis DRS)

Executive functions (letterfluency, Trail Making Test en Stroop)

Depression and/or anxiety (HADS)

Mood states (PANAS/POMS)

Motor symptoms (UPDRS part 3)

Study description

Background summary

Patients with advanced Parkinson`s disease often have response fluctuations and dyskinesias. Bilateral subthalamic nucleus (STN) stimulation is a possibility for reducing motor symptoms. However, negative outcomes have been reported, like the presence of emotional changes.
A possible explanation is alternation of the emotional response after STN stimulation. Lang, Bradley and Cuthbert (1990) define emotions as action dispositions, which are organized around two dimensions: valence and arousal. Emotional response can be measured by affective reports and physiological activity, in particular the startle reflex and psychogalvanic response (PGR). Patients with Parkinson`s disease have a reduced physiological response to negative stimuli. Affective reports were similar to reports of controls (Miller, 2004). Research of the emotional response after bilateral STN stimulation has not been reported yet. Therefore the research question of this study is: Is there a change of emotional response in Parkinson`s disease after bilateral STN stimulation?

Study objective

To gain knowledge about the etiology of emotional changes after bilateral STN stimulation. And also to find out that the research design, where neuropsychological and psysiological aspects are combined, is useful in studying outcomes of STN stimulation.

Study design

The study consists of a controlled, repeated measures design. Patients with Parkinson`s disease who will undergo an STN stimulation will be examined shortly before and two months after the surgery. Patients with Parkinson`s disease who do not undergo surgery will be asked as controls. The auditory and tactile startle reflex will be studied before and after surgery. Moreover pleasant, unpleasant and neutral pictures will be showed. At the same time the PGR is measured. Also, at each picture affective reports on valence and arousal will be determined. Finally, tests concerning general cognitive functioning, executive function, anxiety, depression, mood states and motor symptoms are administered. Each evaluation will take at most two hours.

Study burden and risks

Each evaluation will take at most two hours. First light stress is caused by auditory and tactile stimuli. This procedure contains no risks for the patient. Moreover tests concerning general cognitive functioning, executive function, anxiety, depression, mood states and motor symptoms are also administered.

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

- disease duration et least 5 years or more
- experimental condition: patiënts who undergo an STN stimulation

Exclusion criteria

- dementia (Mattis DRS < 120)
- other serious central nervous system diseases or other diseases.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-10-2006
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL14797.018.06