Deep brain stimulation (DBS) of the nucleus accumbens in treatment-refractory patients with obsessive-compulsive disorder (OCD).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20428

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Obsessive-compulsive disorder (OCD)

Sponsors and support

Primary sponsor: Implantation equipment is provided by Medtronic Europe, Tolochenaz, Switzerland.
No personal funding of research personell.
Source(s) of monetary or material Support: No public funding.

Intervention

Outcome measures

Primary outcome

1. Change on the Y-BOCS;

2. Number of responders, defined as a decrease on the Y-BOCS >35%.

Secondary outcome

1. Hamilton Depression Rating Scale (HDRS-17);

2. Hamilton Anxiety Scale (HAS);

3. Symptom Checklist 90 (SCL-90);

4. Quality of life enjoyment and satisfaction questionnaire;

5. Sheehan Disability Scale (SDS);

6. Clinical Global Impre3ssion (CGI);

7. Y-BOCS checklist.

Study description

Background summary

Objective of the study is to test the hypothesis that bilateral DBS in the nucleus accumbens of patients with severe treatment-refractory OCD can lead to long-term improvement of OCD symptoms and functioning, without unacceptable side-effects.
The study design is a double-blind cross-over trial in which sixteen patients are to be included.
Selected patients are reviewed by an independent approval-board. After electrode implantation an optimisation period is used to test stimulation parameter settings and check for side-effects of stimulation. In the ensuing cross-over period of six weeks without and six weeks with stimulation, the order being determined by randomization, patients are followed closely on an outpatient-basis. Thereafter the study continues with stimulation on in all patients.

Ethical review boards of both hospital have approved the study. An independent safety-committee is informed of all surgeries being performed and all events encountered in the study.

Study objective

DBS in the nucleus accumbens can lead to long-term improvement of obsessive-compulsive symptoms and funtioning, without unacceptable side-effects.

Study design

N/A

Intervention

Stereotactic implantation of bilateral DBS electrodes in the nucleus accumbens, placebo: no stimulation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Primary diagnosis: OCD (300.3) according to DSM-IV criteria using the MINI Plus-interview as diagnostic instrument;

2. Illness duration > 5 years;

3. Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) total > 27, measured twice at least two weeks apart;

4. Disabling severity with substantial funtional impairment according to the DSM-IV criterion

C and a Global Assessment of Function (GAF) score of <45;

5. Age 18 - 65 years;

6. Written informed consent;

7. Able to fully understand the consequences of the procedure (IQ>80);

8. Dutch speaking and able to answer all study questions;

9. Capable to make his or her own choice without coercion;

10. Treatment refractory is defined as no or insufficient response (still fulfilling the inclusion criteria) following:

a. Two treatments with a SSRI at maximum dose for and least 12 weeks, and

b. One treatment with clomipramine at the maximum dose for at least 12 weeks, with assessment of clomipramine/desmethylclomipramine plasma levels to control for sufficient bioavailability, and

c. At least one augmentation trial with an atypical antipsychotic for 8 weeks in combination with a SSRI, and

d. At least one (cognitive) behaviour therapy trial for 16 weeks in combination with an effective drug for the treatment of OCD.

Exclusion criteria

Any of the following: unstable physical condition, Parkinson's disease, dementia, epilepsy, schizophrenia or history of psychosis, alcohol or substance abuse during last 6 months, current tic disorder, antisocial personality disorder, body dismorphic disorder, pregnancy, use of psychiatric medication other than: stable use of one SSRI or clomipramine, one benzodiazepine, one atypical antipsychotic.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2006
Enrollment:	16
Type:	Actual

Ethics review

Positive opinion

Date:	10-03-2006
Application type:	First submission

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
NTR-new	NL565
NTR-old	NTR621
Other	: N/A
ISRCTN	ISRCTN23255677

Study results

Summary results
N/A