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

Gepubliceerd: 10-03-2006 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20428

Bron
NTR

Verkorte titel
N/A

Aandoening

Obsessive-compulsive disorder (OCD)

Ondersteuning

Primaire sponsor: Implantation equipment is provided by Medtronic Europe, Tolochenaz, Switzerland.
No personal funding of research personell.
Overige ondersteuning: No public funding.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	27-03-2006
Aantal proefpersonen:	16
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-03-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL565
NTR-old	NTR621
Ander register	: N/A
ISRCTN	ISRCTN23255677

Resultaten

Samenvatting resultaten

N/A