

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

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| Submission date 07/06/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 07/06/2006 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 30/05/2013 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr P.R. Schuurman

Contact details

Academic Medical Center (AMC)

Department of Neurosurgery

P.O. Box 22660

Amsterdam

Netherlands

1100 DD

+31 (0)20 5669111

p.r.schuurman@amc.nl

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomized, placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obsessive-compulsive disorder (OCD)

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

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 Impression (CGI)
7. Y-BOCS checklist

Completion date

01/07/2007

Eligibility

Key inclusion criteria

1. Primary diagnosis: OCD (300.3) according to Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria using the mini-international neuropsychiatric interview (MINI) plus interview as a 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 functional 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 (intelligence quotient [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 response or insufficient response (still fulfilling the inclusion criteria) following:
 - a. Two treatments with a selective serotonin reuptake inhibitor (SSRI) at a maximum dose for and least 12 weeks
 - 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
 - c. At least one augmentation trial with an atypical antipsychotic for 8 weeks in combination with an SSRI
 - d. At least one (cognitive) behavioural therapy trial for 16 weeks in combination with an effective drug for the treatment of OCD

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Any of the following unstable physical conditions: 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 dysmorphic disorder, pregnancy, use of psychiatric medication other than stable use of one SSRI or clomipramine, one benzodiazepine, one atypical antipsychotic.

Date of first enrolment

27/03/2006

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Center (AMC) (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

University/education

Funder Name

Academic Medical Center (AMC)

Alternative Name(s)

Academic Medical Center, AMC

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/10/2010 | | Yes | No |
| Results article | results | 01/02/2014 | | Yes | No |