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

Submission date
07/06/2006

Recruitment status
No longer recruiting

Registration date
07/06/2006

Overall study status
Completed

Last Edited
30/05/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
27/03/2006

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 a typical 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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
16

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 dismorphic 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)

Sponsor details
P.O. Box 22660
Amsterdam
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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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