Deep brain stimulation for obsessive-compulsive disorder

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Establishing efficacy and safety of the electrodes and implantable pulse generators (IPGs), which are used for deep brain stimulation (DBS) in patients with obsessive-compulsive disorder (OCD).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON50163

Source
ToetsingOnline

Brief title
DBS for OCD

Condition

- Psychiatric disorders NEC

Synonym
obsessive-compulsive disorder; OCD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: deep brain stimulation, efficacy and safety, obsessive-compulsive disorder

Outcome measures

Primary outcome

Change in obsessive-compulsive symptomes (measured as a change of Y-BOCS score compared to baseline)

Secondary outcome

Depressive symptoms (measured with the Hamilton Depression Rating Scale)

Adverse events

DBS settings

Medication use

Study description

Background summary

Deep brain stimulation (DBS) is an effective treatment for obsessive-compulsive disorder (OCD). However, the DBS system used in the Netherlands carries a CE mark for movement disorders, but not for OCD. Therefore, this study aims to register the long term efficacy and safety of the DBS system.

Study objective

Establishing efficacy and safety of the electrodes and implantable pulse generators (IPGs), which are used for deep brain stimulation (DBS) in patients with obsessive-compulsive disorder (OCD).

Study design

Adult patients with OCD, who have responded insufficiently to medication and psychotherapy, are included in a prospective cohort study. The first year of the treatment, the patient is measured 5 times: before DBS surgery (T0), after surgery with stimulation still off (T1), after optimizing DBS settings (T2), after addition of cognitive behavioral therapy (T3), and one year after DBS

surgery (T4). After the first year, the patient is asked to partcipate in a database study. The patient is followed up once a year for the duration of the treatment (LTx) or until OCD is added as an indication to the CE mark of the concerning devices.

Intervention

The patients are treated with deep brain stimulation.

Study burden and risks

In the literature, a low occurrence of severe adverse events is associated with the surgery, device or stimulation. A high occurrence of mild or transient adverse events associated with stimulation has been described. The latter could always be resolved by parameter adjustment or disappeared spontaneously. Participation in the clinical investigation only concerns the administration of semi-structured interviews. This poses no additional risks over those associated with the treatment or device.

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

We will include patients who meet the following inclusion criteria:
- Obsessive compulsive disorder according to DSM-5 criteria
- At least one of the following conditions is met: 1) Y-BOCS score >= 28; 2) Y--BOCS >= 14 in case of solely obsessions or compulsions; 3) Suffering from obsessions or compulsions for at least 8 hours a day (i.e. a score of 4 on item 1 or item 6 of the Y-BOCS)
- Treatment refractoriness is defined as failure of all of the following: 1) at least 2 different types of SSRI*s; 2) clomipramine; 3) addition of an antipsychotic to either an SSRI or clomipramine; 4) an adequate trial of cognitive-behavorial therapy given by a therapist who has experience with OCD; all treatments should be given at therapeutic dosages for adequate duration. On clinical grounds, exceptions to this definition are allowed, but only after consultation with the coordinating center.
- Age: 18 years or older
- Motivated and capable to make the frequent visits to the outpatient clinic, which are necessary for parameter optimization and the CBT.
- Mentally capable to understand the consequences of the procedure and make his or her own choice without coercion

Exclusion criteria

- Primary diagnosis in psychotic spectrum
- Unstable multiple sclerosis (MS)
- Acute brain damage (eg. recent hemorrhage or stroke)
- General contraindications to have surgery

Study design

Design

Study phase:	3
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-03-2020
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	deep brain stimulation
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	13-02-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-02-2025
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389

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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	NL71290.018.19
Other	NL8034