Cyclic deep brain stimulation for obsessive-compulsive disorder

Published: 25-05-2018
Last updated: 13-01-2025

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON55421

Source
ToetsingOnline

Brief title
Cyclic DBS for OCD.

Condition

- Anxiety disorders and symptoms
- Psychiatric therapeutic procedures

Synonym
obsessive-compulsive disorder; OCD

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: innovatiebeurs van het AMC (interne beurs)

Intervention

Keyword: deep brain stimulation, obsessive-compulsive disorder, outcome study

Outcome measures

Primary outcome

1) Clinician rated symptom scales: Yale-Brown Obsessive-Compulsive Scale

(Y-BOCS)

2) Hamilton Depression Rating Scale (HDRS) and Hamilton Anxiety Scale (HAS)

4) battery power and charging frequency

5) adverse events

Secondary outcome

1) Hamilton Depression Rating Scale (HDRS) and Hamilton Anxiety Scale (HAS)

2) battery power and battery usage

3) adverse events1) subtests of the Cambridge Neuropsychological Test Automated

Battery (CANTAB) to assess cognitive functions

4) resting state scalp EEG to assess amplitude, phase stability and

cross-frequency coupling of cortical theta (~4 Hz), alpha (~10 Hz) and gamma

(>40 Hz) EEG oscillations;

5) EQ-5D and WHOQOL to assess quality of life.

Study description

Background summary

Deep brain stimulation (DBS) targeted at the ventral anterior limb of the internal capsule (vALIC) is an effective treatment for refractory obsessive-compulsive disorder (OCD). However, effective DBS for these patients requires relative high voltages and therefore frequent replacement of the

implanted pulse generator (IPG) or, in case of a rechargeable IPG, frequent and long charging sessions. In addition, DBS for OCD comes with a small risk for adverse effects, such as impulsivity, mood swings, tics or other movement disorders, and potential negative effects on cognitive performance. Advancing DBS for psychiatric applications requires optimizing energy efficiency and minimizing adverse event. For the current study, we will test a new method of cyclic (non-continuous) stimulation that will make the IPG become twice as power-efficient, while potentially retaining clinical effects, limiting side-effects and improving cognitive performance.

Study objective

Our primary objective is to compare the effects of cyclic DBS with continuous DBS in OCD patients on 1) symptom severity. Secondary, we will compare the effects on 1) battery life 2) adverse events 3) cognitive performance 4) cortical EEG oscillations related to cognitive control 5) quality of life.

Study design

16 OCD patients currently treated with DBS at the AMC will be included in an 4-week double blind, randomized crossover study. Patients will be randomized to 2 weeks of cyclic DBS followed by 2 weeks of continuous DBS, or vice versa. Symptoms, adverse events, and battery power in patients with a non-rechargeable IPG or battery usage between last 6 charging sessions for patients with a rechargeable IPG will be measured at baseline, after the first crossover block (T1) and after the second crossover block (T2). Also, cognitive performance, EEG and quality of life will be measured at T1 and T2.

Intervention

Continuous DBS, i.e. the patients regular DBS settings
Cyclic DBS, i.e. the regular DBS settings delivered in a cyclic pattern of 0.1 seconds ON and 0.2 seconds OFF.

Study burden and risks

Participants could have a direct benefit, as the studied intervention might lead to more energy-efficient DBS with less side-effects. Participants are already implanted with a DBS system containing the settings for cyclic stimulation; therefore there is no additional surgical risk. The main risk is a potential worsening of clinical symptoms during cyclic DBS, in which case we will offer an admission to our psychiatric department. Additionally, there will be a burden in time for the three study-visits at our department and two telephone calls, which will be a total of 6.5 hours in 4 weeks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1) Subject has a primary diagnosis of OCD, which is treated with deep brain stimulation at the AMC.
2) Subject has completed the period of optimization of DBS settings.
3) Subject has responded to DBS-treatment, defined as an improvement of >25% in Y-BOCS at last follow-up compared to the pre-surgical baseline.
4) Subject has provided informed consent.

Exclusion criteria

Subject is unwilling or unable to comply with all study-required follow-up evaluations.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2018
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	Implantable pulse generator;Activa PC and Activa RC
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	25-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-11-2018
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20728
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	7394
CCMO	NL61011.018.17
OMON	NL-OMON20728