Cyclic versus continuous deep brain stimulation in obsessive-compulsive disorder

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

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20728

Source
NTR

Brief title
Cyclic versus continuous DBS for OCD

Health condition

Obsessive compulsive disorder Deep brain stimulation

Sponsors and support

Primary sponsor: Academic Medical Center - University of Amsterdam
Source(s) of monetary or material Support: Academic Medical Center inovation scholarship

Intervention

Outcome measures

Primary outcome

Obsessive compulsive symptoms measured with the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS).

Secondary outcome

1) Hamilton Anxiety Scale (HAS) and Hamilton Depression Rating Scale (HDRS) 2) battery power and battery usage between charging sessions 3) adverse events 4) subtests of the Cambridge Neuropsychological Test Automated Battery (CANTAB) to assess cognitive functions 5) 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; 6) EQ-5D and WHOQOL to assess quality of life.

Study description

Background summary

Rationale: Deep brain stimulation (DBS) targeted at the ventral anterior limb of the internal capsule (vALIC) is an effective treatment for treatment-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 events. 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.

Objective: Our primary objective is to compare the effects of cyclic DBS with continuous DBS in OCD patients on OCD symptom severity, since optimizing battery life and minimizing adverse events should not be at the cost of lower clinical effectiveness. Secondary, we will compare the effects on 1) Symptoms of depression and anxiety 2) battery life, 3) adverse events, 4) cognitive performance, 5) cortical EEG oscillations related to cognitive control, and 6) quality of life.

Study design and population: 20 OCD patients currently treated with DBS at the AMC will be included in an 4-week double blind, randomized crossover study. In the first phase, 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 will be measured at baseline, after the first crossover block (T1) and after the second

crossover block (T2). In addition, cognitive performance, EEG and quality of life will be measured at T1 and T2. In patients with a rechargeable IPG, data from the last 6 charging sessions will be obtained from the IPG to calculate energy-efficiency (battery usage) between two charging sessions.. At the end of the trial, results will be unblinded after which we will continue the optimal DBS setting (cyclic or continuous) in agreement with the patient.

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

Main study parameters/endpoints: Primary endpoint: Yale-Brown Obsessive-Compulsive Scale (Y-BOCS). Secondary endpoints 1) Hamilton Anxiety Scale (HAS) and Hamilton Depression Rating Scale (HDRS) 2) battery power and battery usage between charging sessions 3) adverse events 4) subtests of the Cambridge Neuropsychological Test Automated Battery (CANTAB) to assess cognitive functions 5) 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; 6) EQ-5D and WHOQOL to assess quality of life.

Study objective

Deep brain stimulation (DBS) targeted at the ventral anterior limb of the internal capsule (vALIC) is an effective treatment for treatment-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 events. 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 design

Baseline, T1 (after 2 weeks) T2 (after 4 weeks)

Intervention

Cyclic DBS (0,1 seconds ON, 0,2 seconds OFF) versus continuous DBS

Contacts

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Eligibility criteria

Inclusion criteria

œ Subject has a primary diagnosis of OCD with DBS implantation performed in the previous years at the AMC.
œ Subject has completed the period of optimization of stimulation settings.
œ 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.
œ Subject has provided informed consent.

Exclusion criteria

œ Subject is unwilling or unable to comply with all study-required follow-up evaluations.
œ Alcohol or substance dependence during the last six months (excluding tobacco use).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2018
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-07-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55421
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7171
NTR-old	NTR7394
CCMO	NL61011.018.17
OMON	NL-OMON55421

Study results