Deep brain stimulation for obsessive compulsive disorder

Gepubliceerd: 18-09-2019 Laatst bijgewerkt: 13-12-2022

DBS leads to a symptom reduction in patients with OCD

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21232

Bron
Nationaal Trial Register

Verkorte titel
DBS for OCD

Aandoening

Obsessive-compulsive disorder

Ondersteuning

Primaire sponsor: Board of directors, Amsterdam UMC (location AMC)
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of responders after one year of treatment. Response is defined as ≥35% reduction of the Y-BOCS score compared to baseline.

Toelichting onderzoek

Achtergrond van het onderzoek

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: Patients with treatment-resistant OCD are enrolled in a multicenter, 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 measured 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.

Inclusion criteria: 1) Obsessive compulsive disorder according to DSM-5 criteria; 2) At least one of the following conditions is met: a) Y-BOCS score ≥ 25, b) Y-BOCS ≥ 13 in case of solely obsessions or compulsions, or c) 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); 3) Treatment refractoriness as agreed upon by a multidisciplinary team of experts and consultation of an independent expert; 4) age must be 18 years or older; 5) mentally capable to understand the consequences of the procedure and make his or her own choice without coercion; 6) written informed consent.

Exclusion criteria: 1) Primary diagnosis in psychotic spectrum; 2) Unstable multiple sclerosis (MS); 3) Acute brain damage (eg. recent hemorrhage or stroke); 4) General contraindications to have surgery

Sample size: This study concerns a registration study to monitor efficacy and safety until OCD is added as an indication to the CE mark of the concerning medical devices. Therefore, all eligible patients with OCD for deep brain stimulation are included. A sample size calculation is not applicable.

Intervention: DBS targeted to the capsular area around the striatum. DBS consists of two phases: neurosurgical implantation of electrodes and an IPG, followed by optimization of electrical parameters of the pulses given off by the electrodes (eg. voltage, frequency or pulse width).

Primary study outcome: Number of responders after one year of treatment. Response is defined as ≥35% reduction of the Y-BOCS score compared to baseline.

Doel van het onderzoek

DBS leads to a symptom reduction in patients with OCD

Onderzoeksopzet

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 measured 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.

Onderzoeksproduct en/of interventie

DBS targeted to the capsular area around the striatum. DBS consists of two phases: neurosurgical implantation of electrodes and an IPG, followed by optimization of electrical parameters of the pulses given off by the electrodes (eg. voltage, frequency or pulse width).

Contactpersonen

Publiek

Academisch Medisch Centrum, Amsterdam
Isidoor Bergfeld

+31208913600

Wetenschappelijk

Academisch Medisch Centrum, Amsterdam
Isidoor Bergfeld

+31208913600

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Obsessive compulsive disorder according to DSM-5 criteria; 2) At least one of the following conditions is met: a) Y-BOCS score ≥ 25, b) Y-BOCS ≥ 13 in case of solely obsessions or compulsions, or c) 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); 3) Treatment refractoriness as agreed upon by a multidisciplinary team of experts and consultation of an independent expert; 4) age must

be 18 years or older; 5) mentally capable to understand the consequences of the procedure and make his or her own choice without coercion; 6) written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Primary diagnosis in psychotic spectrum; 2) Unstable multiple sclerosis (MS); 3) Acute brain damage (eg. recent hemorrhage or stroke); 4) General contraindications to have surgery

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-03-2020
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8034
Ander register	METC AMC : METC2019_230

Resultaten