Deep brain stimulation of the medial forebrain bundle for treatment-resistant depression

No registrations found.

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

Summary

ID

NL-OMON20193

Source
Nationaal Trial Register

Brief title
MFB DBS for TRD

Health condition

Treatment-resistant depression

Sponsors and support

Primary sponsor: Board of directors, Amsterdam UMC (location AMC)
Source(s) of monetary or material Support: ZonMw (nr 636310016); Boston Scientific (24 DBS devices, in kind)

Intervention

Outcome measures

Primary outcome

Difference in scores between active and sham DBS on the Hamilton Depression Rating Scale, 17 items (HAM-D-17, range 0-52 with higher scores indicating more symptoms);

Secondary outcome

Secondary outcomes include percentage of responders after the open label phase (defined as a ≥50% reduction of the baseline HAM-D-17 score), (serious) adverse events, qualtiy of life, (neuro)psychological outcomes and neuro-imaging.

Study description

Background summary

Rationale: Recent pilot studies show efficacy of deep brain stimulation (DBS) in patients with depression is dependent on the distance of the electrode to a specific brain bundle: the superolateral branch of the medial forebrain bundle (slMFB).

Objective: Establishing efficacy of slMFB DBS for TRD by comparing active DBS with sham DBS. Secondary aims are establishing an adverse events profile, establishing effects on quality of life, cost-effectiveness, (neuro)psychological and neuroimaging measures.

Study design: Longitudinal, open-label trial, followed by a randomized, double-blind crossover phase.

Study population: 24 patients with unipolar, treatment-resistant major depression and 24 healthy controls (HC) matched on age, gender and education level will be included.

Intervention: DBS targeted to the slMFB. After the open-label phase patients are randomized to active DBS followed by sham DBS, or vice versa.

Main study parameters/endpoints: 1) difference in scores between active and sham DBS on the Hamilton Depression Rating Scale, 17 items (HAM-D-17, range 0-52 with higher scores indicating more symptoms); Secondary outcomes include percentage of responders after the open label phase (defined as a ≥50% reduction of the baseline HAM-D-17 score), (serious) adverse events, (neuro)psychological outcomes and neuro-imaging.

Follow-up and duration of the study: Over a period of 1.5 years, patients need to visit the hospital eight times: once for screening, and seven times for study visits. These consist of semi-structured interviews, questionnaires, a neuropsychological battery, and magnetic resonance imaging (MRI) scans. The screening takes approximately 7.5 hours (divided over two days), and study visits range from 1 to 4 hours. The total burden in time is approximately 25 hours including the screening. In addition, patients need to visit the outpatient clinic 5-15 times for optimization of DBS parameters.
Healthy controls need to visit the hospital 3 times, for 3-3.5 hours. The total burden in time is approximately 10 hours.

Study objective

Depressive symptom severity is reduced more by active DBS than sham DBS.

Study design

Screening, baseline (before surgery), T1 (after surgery, before active DBS), T2 (after active DBS), T3 (after first crossover phase), T4 (after stabilization phase), T5 (after second crossover phase), T6 (after long-term maintenance phase).

Intervention

Deep brain stimulation (DBS) of the superolateral branch of the medial forebrain bundel (slMFB)

Contacts

Public
Academisch Medisch Centrum, Amsterdam
Isidoor Bergfeld

+31208913600
Scientific
Academisch Medisch Centrum, Amsterdam
Isidoor Bergfeld

+31208913600

Eligibility criteria

Inclusion criteria

1) A primary diagnosis of major depressive disorder (single episode or recurrent; 296.2 or 296.3) according to the DSM-5 criteria; 2) Treatment-resistance, which is defined in detail in Chapter 6.3; 3) HAM-D total ≥ 18; 4) Illness duration > 2 years; 5) Disabling severity with substantial functional impairment; 6) Age: 20-70 years old; 7) Dutch or English speaking and able to answer the study questions; 8) Motivated and capable to attend the study visits; 9) Able to fully understand the consequences of the procedure; 10) Mentally capable to make his or her own choice without coercion; 11) Written informed consent

Exclusion criteria

Exclusion criteria: 1) Bipolar disorder; 2) Schizophrenia / history of psychosis unrelated to MDD; 3) Alcohol or substance abuse (including benzodiazepines) during the last 6 months; 4) Primary and severe personality disorder diagnosed independently from TRD; 5) Explicit suicidal plans requiring hospitalization in a closed ward; 6) Unstable physical condition or general contraindications to have surgery; 7) Depression as a result of acute brain damage (e.g. stroke / hemorrhage); 8) Parkinson's disease, Tourette syndrome, dementia, epilepsy, tic disorder; 9) Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	48
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	03-12-2019
Application type:	First submission

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
NTR-new	NL8211
Other	METC AMC : METC2020_038

Study results