Deep Brain Stimulation in Chronic Treatment refractory Drug Dependence: A Pilot Study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Impulse control disorders NEC
Study type	Interventional

Summary

ID

NL-OMON35020

Source
ToetsingOnline

Brief title
DBS in addiction

Condition

- Impulse control disorders NEC

Synonym
treatment resistant drug dependence, untreatable addiction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: addiction, Deep Brain Stimulation, neuroimaging

Outcome measures

Primary outcome

Primary outcome measurements include subjective craving and illicit drug use.

In addition, urinalysis will be performed to validate self-reported drug use.

Concerning the imaging experiments the outcome will be assessed by changes in

brain activity with fMRI and changes in striatal dopamine D2 binding with

SPECT.

Secondary outcome

Secondary outcomes include social function and quality of life.

Study description

Background summary

Addiction is a chronic relapsing brain disease with severe negative consequences for patients, their environment and society as a whole. Fortunately, a large number of effective interventions is currently available and many patients can be adequately treated. However, like in most other chronic diseases, not all patients respond favourably and additional treatments are needed to help those chronically addicted, treatment refractory patients. As a consequence, many treatment refractory patients remain devoid of effective treatment.

Recently Deep Brain Stimulation has been applied for treatment refractory psychiatric disorders. Deep Brain Stimulation (DBS) is an adjustable, reversible, non-destructive intervention using a surgically implanted medical device, similar to a pacemaker, to deliver carefully controlled electrical pulses to precisely targeted areas of the brain. There is compelling evidence from both experimental human studies that DBS of the NcAcc is potentially effective in the treatment of patients with a substance use disorder.

Until now, the safety and efficacy of DBS for treating substance use disorders

has not been examined. Therefore, the present pilot study aims to test the feasibility, safety and potential efficacy of nucleus accumbens (NcAcc) DBS in chronic, treatment-refractory heroin and/or cocaine dependent patients. In addition, the study aims to understand to changes in brain function related to NcAcc DBS and the relationship between these changes and treatment outcome using functional Magnetic Resonance Imaging (fMRI) and Single Photon Emission Computed Tomography

Study objective

The aims of the study are (1) to establish the feasibility, safety, and potential efficacy of NcAcc DBS in patients with a chronic, treatment refractory heroin and/or cocaine addiction; (2) to explore functional effects of NcAcc DBS in terms of brain activation patterns in response to (neurocognitive) challenges related to addiction and relapse using functional MRI (fMRI) and to study the association between these effects and clinical outcome parameters; (3) to explore the functional effects of DBS in terms of changes in striatal dopamine D2 binding using SPECT and to study the association between these changes and clinical outcome parameters.

Study design

It is a pilot study in which the subjective craving and illicit drug use will be compared over time during different time points in the research.

Neuroimaging study:
Patients will be compared within a randomized double blind within subject study design over two time points in which the stimulator is either on or off. The changes in D2 receptor binding and alterations in BOLD response will be compared over these time points.

Intervention

The intervention of this study will be Deep Brain Stimulation (DBS) in the Nucleus Accumbens (NcAcc) in all participants. Deep Brain Stimulation is an adjustable, reversible, non-destructive intervention using a surgically implanted medical device to deliver carefully controlled electrical pulses to precisely targeted areas of the brain. The stimulation can be programmed and adjusted non-invasively (without surgery) by a trained clinician to maximize symptom control and minimize side effects. The NcAcc has been chosen because both animal and human studies indicate that this location is promising for DBS treatment of addiction and because this location has shown to be safe in DBS studies among humans with other psychiatric disorders such as anxiety, depression, and OCD. In addition, the AMC has ample experience with NcAcc DBS, since more than 20 patients with OCD have been treated following the same

protocol.

Study burden and risks

The greatest burden on the patient during this study is the intervention itself, including (full) detoxification, surgery and the establishment of a new lifestyle without the use of illicit drugs. During the various phases of the study, the time burden on the patient varies from 4 hours in the 1 week surgery phase, through 8 hours in the 8 weeks preparatory phase to almost 20 hours during the 12 week double blind phase. With the exception of the neuroimaging assessments, none of the assessments are very cumbersome. Moreover, none of the assessments is very painful or carries a serious health risk. For the SPECT scans the total radiation dose for each [123I]IBZM scan is 4.8 mSv. Because every patient will get 2 SPECT scans the total radiation dose is 9.6 mSv. This lies below the maximum dose allowed for scientific research (10 mSv/year). Potential risks involved in DBS include the risks associated with the surgical procedures, including the small risk (< 1%) of intracranial haemorrhage or infection and the associated neurological consequences. In addition, some patients may experience temporary but unpleasant sensations around the subcutaneously implanted stimulator and the cables form the stimulator to the electrodes. Finally, some patients may show some temporary neurological symptoms (e.g. eye movement abnormalities) that generally disappear spontaneously or after some fine-tuning of the stimulator.

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

- Chronic course of substance use disorder: minimal duration of 5 years of DSM-IV diagnosis heroin and/or cocaine dependence
- Being treatment refractory despite treatment programs
- Severe dependence: heroin/cocaine use at least 15 days in last month AND poor physical health AND/OR poor mental health AND/OR poor social functioning

Exclusion criteria

- Current major depression, current suicidality, current OCD.
- Current psychosis and no history of psychosis
- (history of) severe neurological disorders
- Contraindication to perform the operation
- Contraindication to participate in fMRI and/or SPECT assesment

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-04-2010
Enrollment:	8
Type:	Anticipated

Medical products/devices used

Generic name:	Activa neurostimulator
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL30889.018.09