Deep brain Stimulation for Addiction.

No registrations found.

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

Summary

ID

NL-OMON26324

Source
Nationaal Trial Register

Health condition

Heroine dependence
Cocaine dependence
drug addiction

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: ZonMw, Grant number 60-60600-97-168

Intervention

Outcome measures

Primary outcome

1. Drug use: gr/day by interview and urine testing;

2. Drug craving: DDQ, OCDUS;

3. Neuropsychological functioning: CANTAB;

4. Changes brain activation: fMRI.

Secondary outcome

1. Changes in eating and sexual activity: interview;

2. Depression: Hamilton depression scale;

3. OCD symptoms: Y-BOCS;

4. Smoking: FTND.

Study description

Background summary

Addiction is a highly prevalent and chronic relapsing disease with severe negative consequences for patients, their environment and society. Not all patients respond to the currently available interventions and therefore additional treatments are needed to help those refractory patients.

Deep brain stimulation (DBS) has shown to be effective in different neurological and psychiatric diseases. Both animal research and observational human studies provide compelling evidence for the potential efficacy of DBS in patients with a substance disorder. DBS of the nucleus accumbens (NAc) is compatible with our neurobiological understanding of addiction based on extensive experimental animal and human research.
This research project aims to establish the feasibility, safety, and potential efficacy of NAc DBS in 8 patients with a chronic, treatment refractory heroin and/or cocaine addiction. Additionally the functional effects of DBS will be explored in several ways; by imaging methods such as fMRI and by neuropsychological testing. Changes found in these three areas will be associated with clinical outcome parameters.

Study objective

Deep brain stimulation of the nucleus accumbens decreases drug use and craving in treatment refractory heroin and/or cocaine dependence.

Study design

1. Baseline (0);

2. After optimalization (1);

3. Phase 1 cross-over trail (2);

4. Phase 2 cross-over trail (3);

5. Maintanence phase (4).

Intervention

Treatment by means of deep brain stimulation of the nucleus accumbens area. Deep brain stimulation (DBS) is a neurosurgical intervention in which implanted electrodes deliver electrical pulses to stereotactically targeted areas of
the brain. The treatment will be given as long as necessary, which might mean their whole lives.
For the research phase there will be a double blinded cross over phase once the DBS has been optimized (between 3-12 months after surgery). In this phase first the DBS will be stay ON or put OFF for 2-6 weeks after which the assessments will take place and secondly the setting of the DBS is reversed (ON/OFF) for 2-6 weeks and again followed by assessments. The order of ON/OFF or OFF/ON will be randomized. Patients will serve as their own controls: assessments of ON condition will be compared to assessments with OFF condition. Both researcher and patients are blind for DBS setting during trail.

Contacts

Public
Department of Psychiatry
Academic Medical Center
University of Amsterdam
Meibergdreef 5
Judy Luigjes
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 8913706
Scientific
Department of Psychiatry
Academic Medical Center
University of Amsterdam
Meibergdreef 5
Judy Luigjes
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 8913706

Eligibility criteria

Inclusion criteria

1. Minimal duration of 5 years of the DSM-IV diagnosis heroin and/or cocaine dependence;

2. Treatment refractory on other evidence based interventions;

3. Severity of the current dependence diagnosis is indicated by:

A. Heroin and or cocaine use at least 15 days in the last month; AND;

B. Poor physical health (MAP-HSS > 8); AND/OR;

C. Poor mental health (SCL-90 > 41 (male) or > 60 (female); AND/OR;

D. Poor social function with at least six days of illegal activities in the previous month and/or at least six days in the previous month without personal contact with a non-drug-using person.

Exclusion criteria

1. Current suicidality;

2. Current psychosis and no history of psychosis;

3. (History of) severe neurological disorders, e.g. Parkinson's disease, CVA, dementia;

4. Contraindication to perform the operation;

5. Contraindication to participate in fMRI and/or SPECT assessments.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	8
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-04-2012
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	NL3267
NTR-old	NTR3420
Other	METC AMC : 2009_322
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

1. Luigjes J, van den Brink W, Feenstra M, van den Munckhof P, Schuurman PR, Schippers R, e.a. Deep brain stimulation in addiction: a review of potential brain targets. Mol. Psychiatry 2011 doi: http://www.ncbi.nlm.nih.gov/pubmed/21931318;
2. Valencia-Alfaonso CE, Luigjes J, Smolders R, Cohen MX, Levar N, Mazaheri A, van den Munckhof P, Schuurman PR, van den Brink W, Denys D. Effective deep brain sitmulation in heroin addiction: a case report with complementary intracranial electroencephalogram. Biol Psychiatry 2012 71 e35-37