

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Investigation of Deep Brain Stimulation of Nucleus Accumbens for Treatment-Refractory Obsessive-Compulsive Disorder

Protocol summary

Study aim

Investigation of Deep Brain Stimulation for Treatment of Refractory Obsessive-Compulsive Disorder patients and their neuropsychological performance

Design

A study on 5 Refractory Obsessive-Compulsive Disorder patients

Settings and conduct

Before implantation the severity of OCD, Personality, and cognition of patient will be evaluated. The electrodes will be surgically bilateral implanted in the nucleus accumbens in Rasoul Akram Hospital, Iran University of Medical Sciences. Patients will receive stimulation and all outcomes will be recorded in 1 and 2 weeks after implantation. In addition, the outcomes will be recorded in every 1 month for 12 months follow up in school of Behavioral Sciences and Mental Health.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age: 16-65 Diagnosis and Severity: Sever and chronic OCD for at least 5 years, Yale-Brown scale at least 25, Hamilton scale at least 17, IQ more than 85 Treatment refractoriness: Not response for SSRI for 12 weeks, clomipramine 12 weeks, atypical antipsychotics for 6 weeks and CBT for 16 sessions
Exclusion criteria: Psychotic disorders, Dementia, Bipolar disorders, Autism, Parkinson, Substance use disorders, Personality Disorders, Pregnancy

Intervention groups

Deep Brain Stimulation and implantation of electrodes in Nucleus Accumbens

Main outcome variables

OCD severity; Depression and anxiety; cognitive performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161026030510N2**

Registration date: **2019-01-08, 1397/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-08, 1397/10/18**

Update count: **0**

Registration date

2019-01-08, 1397/10/18

Registrant information

Name

Reza Arezoomandan

Name of organization / entity

Addiction Department, School of Behavioral Sciences and Mental Health (Institute of Tehran Psychiatr

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1658

Email address

arezoomandan.r@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2020-09-23, 1399/07/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of Deep Brain Stimulation of Nucleus Accumbens for Treatment-Refractory Obsessive-Compulsive Disorder

Public title

Deep Brain Stimulation for Treatment of Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 16-65 Diagnosis and Severity: Sever and chronic OCD for at least 5 years, Yale-Brown scale at least 25, Hamilton scale at least 17, IQ more than 85 Treatment refractoriness: Not response for SSRI for 12 weeks, clomipramine 12 weeks, atypical antipsychotics for 6 weeks and CBT for 16 seasons

Exclusion criteria:

Psychotic disorders, bipolar disorder, autism disorder, substance abuse, epilepsy, dementia, Parkinson's disease and pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

14665-354

Approval date

2018-11-24, 1397/09/03

Ethics committee reference number

IR.IUMS.REC.1397.538

Health conditions studied**1****Description of health condition studied**

Obsessive-Compulsive Disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

2**Description of health condition studied**

Cognitive performance

ICD-10 code

F99

ICD-10 code description

Diseases of the nervous system

Primary outcomes**1****Description**

Severity of OCD

Timepoint

every month

Method of measurement

Yale- Brown scale

2**Description**

Neuropsychological performance

Timepoint

every month

Method of measurement

Neuropsychological tools

Secondary outcomes**1****Description**

Side effects, such as headache, nausea and...

Timepoint

during the intervention and 2 months after that

Method of measurement

questionnaire or observation

Intervention groups**1****Description**

Deep brain stimulation (DBS), a neurosurgical procedure involving the implantation of a medical device called a neurostimulator, which sends electrical impulses,

through implanted electrodes, to specific targets in the brain (nucleus accumbens) and stimulate this nucleus. After surgery, stimulation will be 130 Hz, at pulse widths of 90 and 150 us and at 2-7 V. Stimulation will adjust in optimization phase base on improvements of patients and clinical outcomes.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center**Name of recruitment center**

Rasol Akram Hospital

Full name of responsible person

Reza Arezoomandan

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research of Iran University of Medical Sciences

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Hemmat Highway

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Reza Arezoomandan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Addiction

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Full name of responsible person

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Position

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Other areas of specialty/work

Neuroscience

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Reza Arezoomandan

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Clinical and neuropsychological outcomes

When the data will become available and for how long

2019

To whom data/document is available

Academic Researchers

Under which criteria data/document could be used

Academic Researchers

From where data/document is obtainable

Email

What processes are involved for a request to access data/document

Academic Email

Comments