

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparative Evaluation of Three Noninvasive Neuromodulation Antidepressant Methods in Major Depressive Disorder Treatment in Patients Referred to Hospitals and Treatment Centers of Psychiatric Patients in Zanjan Province in Year 2023.

Protocol summary

Study aim

Comparison of non-invasive brain stimulation methods to find the best and most cost-effective methods of treating depression

Design

This study is a parallel design randomized controlled clinical trial.

Settings and conduct

The sample size in the mentioned study is 100 patients. The diagnosis of the disease is based on having major depression criteria based on the DSM-5 criteria, which will be done through a semi-structured clinical interview and confirmation of the diagnosis by a psychiatric specialist. For the intervention group, in addition to the routine treatment of depression with SSRI (sertraline), 3 methods of tDCS, ECT and rTMS will be used, which are eligible for additional treatment by the relevant psychiatrist..

Participants/Inclusion and exclusion criteria

Entry requirements: 1-Having DSM-5 diagnostic criteria for patients who are currently being treated with one of the SSRI drugs. 2-Being 18 to 30 years old 3-Receiving a fixed dose of SSRI drugs that are under medical treatment for at least 4 weeks. Non-entry requirements: 1- There is another diagnosis in axis 1 based on DSM-5 2- Comorbidity with mental retardation 3- Inability to communicate 4- Dependence or substance abuse in the past month

Intervention groups

The research environment in the current study includes Dr. Beheshti Hospital and psychiatric centers that are equipped with at least one of the three treatment methods: ECT, rTMS, or tDCS. And the research population includes people referred with a diagnosis of major depressive disorder and are currently receiving SSRI drugs and are indicated to receive any of the three

methods of brain stimulation by each of the psychiatrists working at Dr. Beheshti Hospital.

Main outcome variables

Improvement of depression rate and severity based on Beck test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221224056914N1**

Registration date: **2023-02-06, 1401/11/17**

Registration timing: **prospective**

Last update: **2023-02-06, 1401/11/17**

Update count: **0**

Registration date

2023-02-06, 1401/11/17

Registrant information

Name

Dauvoud Maukoie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3354 4001

Email address

dmd_medical@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of Three Noninvasive Neuromodulation Antidepressant Methods in Major Depressive Disorder Treatment in Patients Referred to Hospitals and Treatment Centers of Psychiatric Patients in Zanjan Province in Year 2023.

Public title

Comparison of Three Noninvasive Neuromodulation Antidepressant Methods in Major Depressive Disorder Treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having DSM-5 diagnostic criteria for patients, who are currently being treated with one of the SSRI drugs Being 18 to 30 years old Receiving a fixed dose of SSRI drugs that are under medical treatment for at least 4 weeks

Exclusion criteria:

Unwillingness to cooperate during the study Incidence of severe side effects

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Clients are assigned to four groups through random block method

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, principal investigator, health care personnel, responsible for data collection with a double-blind method

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Zanjan University of Medical Sciences

Street address

Gavazang Road, Zanjan University of Medical Science

City

Zanjan

Province

Zanjan

Postal code

4513615788

Approval date

2022-10-31, 1401/08/09

Ethics committee reference number

IR.ZUMS.REC.1401.209

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

Major depressive disorder

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

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

Depression score in Beck questionnaire

Timepoint

Measuring depression severity at the beginning and end of the course

Method of measurement

Beck depression questionnaire

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

Side effects

Timepoint

Before starting the study, after completing the intervention period

Method of measurement

Beck depression questionnaire

Intervention groups

1

Description

Control group: The group that receives one of the drugs of the SSRI class with an antidepressant dose

Category

Treatment - Drugs

2

Description

Intervention group: The first intervention: the group that receives ECT for 6 sessions every other day.

Category

Treatment - Devices

3

Description

Intervention group: The second intervention: the group that receives rTMS for 20 sessions on a daily basis.

Category

Treatment - Devices

4

Description

Intervention group: The third intervention: the group receiving tDCS for 10 sessions.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti hospital

Full name of responsible person

Davoud Maukoie

Street address

Arg Square, Beheshti hospital

City

Zanjan

Province

Zanjan

Postal code

4513615788

Phone

+98 24 3353 4500

Email

www.ddm_medical@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Seyed Abolfazl Ghoreishi

Street address

Arg Square, Beheshti hospital

City

Zanjan

Province

Zanjan

Postal code

4513615788

Phone

+98 24 3353 4500

Email

www.ddm_medical@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Davoud Maukoie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Arg square, Beheshti hospital

City

Zanjan

Province

Zanjan

Postal code

4513615788

Phone

+98 24 3353 4500

Email

www.ddm_medical@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Seyed Abolfazl Ghoreyshi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Arg square, Beheshti hospital

City

zanjan

Province

Zanjan

Postal code

4513615788

Phone

+98 24 3353 4500

Email

Dr.ghoreishi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dauvoud Maukoie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Arg square, Beheshti hospital

City

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Province

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Postal code

4513615788

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www.ddm_medical@yahoo.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information about the measurement of depression intensity reduction in different brain stimulation methods can be published.

When the data will become available and for how long

The access period starts 3 months after the results are published

To whom data/document is available

All people who work in the field of psychiatry have access to information.

Under which criteria data/document could be used

Doctors working in psychiatric centers can access the information.

From where data/document is obtainable

To receive study documents, refer to the Psychiatry Department of Beheshti Zanjan Hospital.

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

After going to the psychiatry department and making a written request to the director of the psychiatry department and confirming the request by the relevant person, he can view the documents.

Comments