Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Provinence 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

ddm_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 Provinence in Year 2023.

Public title
Comparation 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
Dauvoud Maukoie
Street address
Arg Square, Beheshti hospital
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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
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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
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
Dauvoud Maukoie
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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Associate Professor

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Person responsible for updating data

Contact

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Dauvoud Maukoie

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Arg square, Beheshti hospital

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Zanjan

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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