Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of repetitive transcranial magnetic stimulation on negative symptoms in schizophrenic patients

Protocol summary

Study aim
Evaluation of the therapeutic effect of repetitive Transcranial Magnetic Stimulation (rTMS) on the negative symptoms of schizophrenia
Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment
Settings and conduct
Schizophrenic patients referred to Shahid Beheshti Hospital, Zanjan in rTMS ward received active or sham stimulation. The patient and the therapist do not know the type of stimulation. Only rTMS operator is aware of the type of stimulation.
Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients with schizophrenia with negative symptoms, Be treated with antipsychotics, The patient is in the maintenance phase. Criteria for not entering: The patient is pregnant, has depression, has a history of seizures.
Intervention groups
Schizophrenic patients with negative symptoms are divided into two groups of 33 people. The intervention group receives real stimulation. The control group receives sham stimulation.
Main outcome variables
Negative symptoms of schizophrenic patients like poverty of speech, apathy, social withdrawal

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211029052909N1**
Registration date: **2021-12-11, 1400/09/20**
Registration timing: **prospective**

Last update: **2021-12-11, 1400/09/20**
Update count: **0**
Registration date
2021-12-11, 1400/09/20

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-04, 1401/01/15
Expected recruitment end date
2023-04-04, 1402/01/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of repetitive transcranial magnetic stimulation on negative symptoms in schizophrenic patients

Public title
Evaluation of the therapeutic effect of rTMS on negative symptoms in schizophrenic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Patients with schizophrenia with negative symptoms Be treated with antipsychotics The patient is in the maintenance phase

Exclusion criteria:

Depression Seizure Pregnancy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. 66 patients will be selected to participate in the study by being available and passing the admission conditions. But assigning them to each treatment group will be simple randomization. For randomization with the help of Excel software by generating binomial distribution and 50% probability for n = 66 we produce codes 0 and 1. In this way, 33 codes 0 and 33 codes 1 are generated equally. Each participant gets a 0 or 1 code completely randomly and with a 50% probability. Code 0 is considered as the control group and code 1 is considered as the intervention group. In this way, the type of treatment for each person before entering the study and observation is determined by each member of the research team.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double blind. This means that the researcher and the patient do not know the type of treatment. Due to the fact that the treatment can be performed on the patient by the rTMS operator, the double blind condition can be applied accurately. It is noteworthy that due to the double blind of the study, only the rTMS operator and the statistician know how to codify and assign patients. Patients have already read and signed the informed consent form. All patients are connected to the rTMS device and the cap of the device is placed on their head. No patient is aware of the type of stimulation (active or sham). The rTMS operator knows the type of stimulation. For patients receiving active stimulation, the device is set to 10 Hz. For patients receiving sham stimulation, the device is set to 0 Hz.

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

Darvazeh Arg

City

Zanjan

Province

Zanjan

Postal code

4513615788

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

IR.ZUMS.REC.1400.265

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Negative symptoms in schizophrenic patients like poverty of speech, apathy, social withdrawal

Timepoint

One day before starting treatment، One day after the end of treatment, Three weeks after the end of treatment

Method of measurement

The Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

1

Description

Score obtained from Positive and Negative Syndrome Scale

Timepoint

One day before starting treatment،, One day after the end of treatment, Three weeks after the end of treatment

Method of measurement

PANSS

Intervention groups

1

Description
Intervention group: Patients were treated with active rTMS. 15 active rTMS sessions with a frequency of 10 Hz, 3 times a week for 5 consecutive weeks. The cap of the device is placed on the patient's head and they receive stimulation in the lateral dorsolateral prefrontal cortex.
Category
Treatment - Other

2

Description
Control group: Patients were treate with sham. Patients connect to the rTMS device and the cap of the device is placed on the patients' heads, but they receive sham stimulation. 15 sham rTMS session with a frequency of 0 Hz, 3 times a week for 5 consecutive weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital, Zanjan
Full name of responsible person
Parisa Entezari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Vice chancellor for research,Zanjan University of Medical Sciences.Dr.Alereza Shoghli
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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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The data can be published after the individuals are not identified

When the data will become available and for how long
When publishing results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
For scientific research

From where data/document is obtainable
Library of Zanjan University of Medical Sciences

What processes are involved for a request to access data/document
Visit the university library

Comments