

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of repetitive Transcranial Magnetic Stimulation (rTMS) on craving in patient with substance dependence

Protocol summary

Study aim

Evaluation of the therapeutic effect of repetitive Transcranial Magnetic Stimulation (rTMS) on craving in patient with substance dependence

Design

Clinical trial with control group with parallel group, double blinded, randomized

Settings and conduct

Patients with diagnosis of Substance Use Disorder, referred to Shahid Beheshti Hospital, Zanjan in rTMS ward received active or sham stimulation. The patient and researcher do not know the type of stimulation. Only rTMS operator and statistician aware of the type of stimulation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diagnosis of Substance Use Disorder according to criteria of DSM-5 and absence of multi substance use that do not receive any medicine during the treatment. Criteria for not entering: The patient be pregnant or have (has) another psychiatric disease, neurological disease (seizure...) or sever physical illness and also presence of metal implants, pacemaker, inner ear prothesis.

Intervention groups

Patient with diagnosis of Substance Use Disorder according to criteria of DSM-5 are divided into two groups of 18 peoples. The intervention group receive real stimulation. The control group receive sham stimulation.

Main outcome variables

Craving in patients with Substance Use Disorder that is measured with the scale of measuring craving for momentary consumption of substance with DDQ (Desire for Drug Questionnaire).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230306057642N1**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

Registration date

2023-06-26, 1402/04/05

Registrant information

Name

Nafiseh Bay

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3573 0801

Email address

nafise_bay@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-08, 1402/04/17

Expected recruitment end date

2023-10-09, 1402/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of repetitive Transcranial Magnetic Stimulation (rTMS) on craving in patient with substance dependence

Public title

Evaluation of the therapeutic effect of repetitive

Transcranial Magnetic Stimulation (rTMS) on craving in patient with substance dependence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with diagnosis of Substance Use Disorder (SUD) according to criteria of DSM-5 Absence of multi substance use People should not receive any medicine during the treatment

Exclusion criteria:

Simultaneous diagnosis of every other psychiatric illness according to the criteria of DSM-5 Neurological disease such as seizure, stroke, cerebral vascular disease Presence of metal implants, pacemaker, inner ear prosthesis Pregnancy Severe physical illness such as infection, malignancy or unstable medical conditions

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: 36 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 $n=36$ we produce codes 0 and 1. In this way, 18 codes 0 and 18 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 is determined before entering the study and observation by each member of the research team. It should be mentioned that due to the double blinding of the study, only the rTMS operator and statistician know how to code and assign patients.

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 should be mentioned that due to the double blinding of the study, only the rTMS operator and statistician know how to code 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

Dr sobooti Blv

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2022-11-24, 1401/09/03

Ethics committee reference number

IR.ZUMS.REC.1401.235

Health conditions studied

1

Description of health condition studied

Substance Use Disorder

ICD-10 code

F11.2

ICD-10 code description

Opioid dependence Cannabis dependence

Primary outcomes

1

Description

Craving in patients with substance use disorder

Timepoint

One day before starting treatment, one day after the end of treatment, two months after the end of treatment.

Method of measurement

Desire for Drug Questionnaire (DDQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who are treated with active rTMS, receive 12 active rTMS sessions with a frequency of 10 Hz, 3 times a week for 4 consecutive weeks. The cap of the device is placed on the patient's head, and they receive stimulation in the Left Dorsolateral Prefrontal Cortex (Left DLPFC).

Category

Treatment - Other

2

Description

Control group: Patients receiving sham stimulation. Patients connect to the rTMS device, and the cap of the device is placed on the Patients head, but they receive sham stimulation. 12 sham rTMS session with a frequency of 0 Hz, 3 times a week for 4 consecutive weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Zanzan

Full name of responsible person

Farzaneh Araghi

Street address

Besat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

Reasearch assistant of Zanzan University of Medical Sciences Dr. Samad Nadri

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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

Zanzan 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

Zanzan University of Medical Sciences

Full name of responsible person

Elham Faghih Zadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Mina Shabani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Full name of responsible person

Nafiseh Bay

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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 institution

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