

# 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

##### City

Zanzan

##### Province

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##### Postal code

4513615788

##### Phone

+98 24 3354 4001

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##### Email

beheshti@zums.ac.ir

##### Web page address

<http://beheshti.zums.ac.ir>

## 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

#### Street address

Dr. Sobooti Blv

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medicine@zums.ac.ir

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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

##### Street address

Faculty of Medicine, Karmandan town, Mahdavi Blv

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Mina Shabani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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Shahid Beheshti Hospital, Darvazeh Ark, Besat street

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## Person responsible for updating data

**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Nafiseh Bay

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

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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**