

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of rTMS device with drug therapy on the improvement of cognitive impairment in patients with generalized anxiety disorder

Protocol summary

Study aim

Overall Objective: To evaluate the effect of rTMS device (repetitive Transcranial Magnetic Stimulation) on recovery of patients with generalized anxiety disorder in Yazd

Design

Clinical trial with control group, with parallel groups, without blinding, on 60 patients

Settings and conduct

Patients in the intervention group will receive medication and rTMS, and patients in the control group will receive medication alone. The number of rTMS sessions is ten sessions that will be performed during 2 weeks and the patients in both groups will be treated with two drugs, paroxetine 20 and trimipramine (a drug from the TCA class). This study will be performed in Bahman psychiatric hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients in the age range of 15-55 years with generalized anxiety disorder, without previous treatment history Exclusion criteria: under 15 years old or over 55 years old, presence of metal accessories or prostheses in the body, traditional or industrial drug addiction, having underlying diseases such as diabetes and hypertension, drug use, anxiety and severe restlessness or Severe insomnia, having dementia

Intervention groups

The intervention group includes 30 patients using rTMS and drug therapy and the control group includes 30 patients undergoing drug treatment alone.

Main outcome variables

Cognitive Disorder Score on Cognitive Disorder Test (MMSE)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210328050785N1**

Registration date: **2021-08-02, 1400/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-02, 1400/05/11**

Update count: **0**

Registration date

2021-08-02, 1400/05/11

Registrant information

Name

Mahtab Meydani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3725 1785

Email address

mahtabmeydani2014@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-18, 1400/04/27

Expected recruitment end date

2021-08-18, 1400/05/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of rTMS device with

drug therapy on the improvement of cognitive impairment in patients with generalized anxiety disorder

Public title

Effect of rTMS in treatment of generalized anxiety disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with generalized anxiety disorder in the age range of 15-55 years Patients agree to enter the study The first action of patients in the treatment of their disease

Exclusion criteria:

Age under 15 or over 55 years Existence of metal accessories or prostheses in the body Traditional or industrial drug addiction Having comorbid disease such as diabetes and high blood pressure Severe anxiety and restlessness or severe insomnia Taking any medication in the patient's history

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups by simple random sampling. The selection of individuals and their placement in dual groups will be random, so that after confirming the necessary conditions to enter the study, patients are selected sequentially, the first patient in the first group, the second patient in the second group, and Likewise, patients will be placed in separate groups. The number of patients in the two groups will be equal.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Yazd Islamic Azad University

Street address

No. 2, Rose Alley., Imam Hossein Square

City

Yazd

Province

Yazd

Postal code

8916184719

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.IAU.YAZD.REC.1400.003

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

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

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

Cognitive impairment score in (MMSE) Mini-Mental State Exam, cognitive impairment test

Timepoint

Measurement of cognitive impairment score (before the start of the study) and 2 and 4 weeks after the end of the study

Method of measurement

MMSE Cognitive Disorder Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 10 sessions of treatment with repetitive transcranial magnetic stimulation (rTMS) over 2 weeks (5 days per week). Each treatment session will last about 45 minutes.

Category

Treatment - Devices

2**Description**

Control group: Common drug treatment of the disease includes the use of 2 drugs paroxetine 20 mg (Paroxetine) and trimipramine 25 mg (Trimipramine), which will be done in the same way in the intervention group. Paroxetine 20 once a night and trimipramine 25 in

case of insomnia One will be used each night. Both drugs will be prescribed to patients in pill form.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bahman Psychiatric Hospital

Full name of responsible person

Mojtaba Yassini

Street address

Bahman Psychiatric Hospital, Kashani St, Yazd Town

City

Yazd

Province

Yazd

Postal code

8913783111

Phone

+98 35 3629 2300

Fax

+98 35 3623 8080

Email

admin@bahmanclinic.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

احمد شجرى

Street address

Unknown Martyrs Blvd, Safaieh Area, Yazd Town

City

Yazd

Province

Yazd

Postal code

8915813135

Phone

+98 35 3187 1000

Email

info@iauyazd.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Mahtab Meydani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No. 2, Rose Alley., Imam Hossein Square

City

Yazd

Province

Yazd

Postal code

8916184719

Phone

+98 35 3725 1785

Email

mahtabmeydani2014@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Afshin Ataeian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Taleghani Blvd

City

Yazd

Province

Yazd

Postal code

8913835699

Phone

+98 35 3626 2889

Email

dr.ataeian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahtab Meydani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No. 2, Rose Alley., Imam Hossein Square

City

Yazd

Province

Yazd

Postal code

8916184719

Phone

+98 35 3725 1785

Email

mahtabmeydani2014@gmail.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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as information about the main outcome (MMSE cognitive impairment score), can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

One must be a member and researcher of a study organization and be employed in that center. The purpose of accessing the data should be to find a new treatment or to better understand the disease and help improve the quality of life of patients. It should not be just for the benefit and use of study information. Provide the necessary evidence that indicates the conduct of the research process.

From where data/document is obtainable

Mahtab Meydani mahtabmeydani2014@gmail.com

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

Contact the person holding the research work (Afshin Ataeian or Mahtab mey dani) and fully state their purpose and characteristics and provide sufficient evidence to prove the status of being a researcher and working in a study center.

Comments