Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Province
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
احمد شجری

Street address
Unknown Martyrs Blvd, Safaieh Area, Yazd Town

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Yazd

Province
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8915813135

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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

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Person responsible for scientific inquiries

Contact

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Afshin Ataeian

Position
Assistant professor

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Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity
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Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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 meydani) 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