

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the efficacy of repetitive transcranial magnetic stimulation in the treatment of patients with functional neurological symptoms (psychological non-epileptic seizure subtype)

Protocol summary

Study aim

Determination of the Effectiveness of repetitive Transcranial Magnetic Stimulation(rTMS) on Psychological Non-Epileptic Seizure Symptoms, Symptoms of Depression, and Quality of Life in Patients with Functional Neurological Symptom Disorder (Psychological Non-Epileptic Seizure subtype)

Design

This study is a randomized, placebo-controlled, double-blind, parallel-groups clinical trial.

Settings and conduct

Thirty patients with psychological nonepileptic seizures were selected from referrals to the neuropsychiatric clinic of Imam Khomeini Hospital in Tehran based on inclusion and exclusion criteria and referred to the rTMS center. In this center, patients are randomly divided into two groups of experimental and control. Patients, researchers, and data analysts are blind to the randomization. The therapeutic and simulated sessions were performed on the experimental and control groups, respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients over 18 years of age with non-epileptic seizure disorder Exclusion criteria: a history of seizures in the patient or his family, Use of seizure threshold lowering drugs, epileptiform changes in long-term electroencephalographic monitoring, suicidal ideation and recent suicidal attempt, psychosis, pregnancy, and metal objects within 30 cm of the coil

Intervention groups

The experimental group received 12 sessions of rTMS and the control group received 12 simulated sham rTMS sessions.

Main outcome variables

Changes in severity of epileptiform symptoms, depression and quality of life of experimental compared to control group

General information

Reason for update

Acronym

rTMS in PNES

IRCT registration information

IRCT registration number: **IRCT20200225046611N1**

Registration date: **2020-04-01, 1399/01/13**

Registration timing: **prospective**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

Registration date

2020-04-01, 1399/01/13

Registrant information

Name

Mohammad Arbabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-05, 1399/01/17

Expected recruitment end date

2021-01-06, 1399/10/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the efficacy of repetitive transcranial magnetic stimulation in the treatment of patients with functional neurological symptoms (psychological non-epileptic seizure subtype)

Public title
Repetitive transcranial magnetic stimulation in psychological non-epileptic seizure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients over 18 years old with psychological non-epileptic seizure based on DSM5
Exclusion criteria:
 True seizure or epileptiform changes in electroencephalographic long term monitoring Suicide thought Use of Lowering seizure threshold drugs Risk of new suicide attempt Psychosis Personal or family history of seizure Metal objects within 30 cm of the coil such as: aneurysm clips, cervical or cerebral stents, cardiac pacemaker or defibrillators, cochlear implants, Face tattoo using magnetic field sensitive ink

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
block randomization Randomization unit: individual Randomization instrument: random allocation software Random sequences using quadratic blocks Allocation concealment with software

Blinding (investigator's opinion)
Double blinded

Blinding description
After examining the inclusion and exclusion criteria, the researcher will refer patients to the rTMS unit. In this unit by the therapist, referral patients are divided into two groups of test and control using random numbers. Some receive rTMS treatment and some sham TMS. Intervention in control group designed the same as real treatment that means the patient is in a chair and the coil is placed on his head but magnetism wouldn't used. The evaluator who asks the patient the questionnaire questions before and after the intervention and the data analyzer will not know which patients are in the test or control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

City

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Province

Tehran

Postal code

1419733141

Approval date

2020-02-05, 1398/11/16

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.851

Health conditions studied

1

Description of health condition studied

Functional neurological symptom disorder (Psychogenic non-epileptic seizure subtype)

ICD-10 code

F44.4

ICD-10 code description

Conversion disorder with motor symptom or deficit

Primary outcomes

1

Description

Psychological non-epileptic seizures severity

Timepoint

At the beginning of the study (before the intervention), immediately after the intervention and two months later

Method of measurement

Clinical Global Impression

Secondary outcomes

1

Description

Depressive severity
Timepoint
At the beginning of study(before intervention),
immediately after intervention and two months later
Method of measurement
Beck's depression inventory

2

Description
Quality of life
Timepoint
At the beginning of study(before intervention),
immediately after intervention and two months later
Method of measurement
WHO Quality of Life-BREF

Intervention groups

1

Description
Intervention group: Stimulation with rTMS Variant 2 from NEROSOF Russia company by 10 Hz frequency, 12 sessions for one month, 25 minutes per session, 1200 stimulations per day, with appropriate stimulation threshold for each individual using eight coils and over The right temporo-parietal junction will be performed.
Category
Treatment - Devices

2

Description
Control group: patients in this group sit on the rTMS chair for 12 months for 25 minutes but do not receive any magnetic stimulation.After completion of the study, the group will receive routine treatment if symptoms persist.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Mohammad Reza Shegarf Nakhaie
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
nimad
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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Arbabi
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Other areas of specialty/work
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

patients' data can be shared after unidentifiable and deleted names

When the data will become available and for how long

Access will begin 6 months after the results are published

To whom data/document is available

Data will be available only to researchers working in academic and scientific centers.

Under which criteria data/document could be used

Documentation is only available for meta-analysis studies

From where data/document is obtainable

Access information on request at arbabimo@tums.ac.ir

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

Applicants must identify their scientific and academic identities and clearly state their intention to request information for use in meta-analytic research.

Comments