

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessing clinical effectiveness of cerebellar repetitive transcranial magnetic stimulation (rTMS) on severity of motor signs of essential tremor.

Protocol summary

Study aim

To evaluate the effectiveness of low frequency repetitive transcranial magnetic stimulation (rTMS) of the cerebellum on essential tremor

Design

Randomized double blind sham controlled crossover clinical trial

Settings and conduct

Patients visited at the Neurology Specialty Clinic of Mashhad Medical University. patients and outcome assessor were blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having a diagnosis of essential tremor (ET) based on Movement Disorder Society criteria, involving at least one hand; 18 years or above; cognitively eligible to give informed consent of participation in the trial. Exclusion criteria: Cardiac pace-maker or other implanted magnetic device or having other contraindications of performing a routine non-contrast MRI; skin defect at the occipital area preventing placement of a coil; Currently pregnant or plan for pregnancy in the next 6 months; History of seizure; Other comorbid medical conditions capable of producing or enhancing tremor; advanced cardiac, renal, hepatic or other disabling conditions making patient physical unable to participate in examination and receiving the intervention; Use of new drugs with potential effect on tremor

Intervention groups

900 pulses of 1 Hz rTMS on 90% of resting motor threshold (RMT) delivered over each cerebellar hemisphere for 5 consecutive days

Main outcome variables

Tremor severity based on Fahn-Tolosa-Marin scale

General information

Reason for update

To update the trial status

Acronym

Cerebellar rTMS for essential tremor

IRCT registration information

IRCT registration number: **IRCT2015100824428N1**

Registration date: **2016-04-01, 1395/01/13**

Registration timing: **prospective**

Last update: **2019-12-25, 1398/10/04**

Update count: **1**

Registration date

2016-04-01, 1395/01/13

Registrant information

Name

Nahid Olfati

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 3842 9828

Email address

olfatin921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor, Mashhad University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

2016-05-21, 1395/03/01
Actual recruitment end date
 2017-11-22, 1396/09/01
Trial completion date
 2018-03-22, 1397/01/02

Scientific title
 Assessing clinical effectiveness of cerebellar repetitive transcranial magnetic stimulation (rTMS) on severity of motor signs of essential tremor.

Public title
 Assessing the effectiveness of repetitive Transcranial Magnetic Stimulation (rTMS) of the cerebellum in treatment of essential tremor.

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having a diagnosis of essential tremor (ET) based on Movement Disorder Society criteria Involvement of at least one hand Cognitively eligible to give informed consent of participation in the trial 18 years or above
Exclusion criteria:
 Cardiac pace-maker or other implanted magnetic device or having other contraindications of performing a routine non-contrast MRI Skin defect at the occipital area preventing placement of a coil Currently pregnant or plan for pregnancy in the next 6 months History of seizure Other comorbid medical conditions capable of producing or enhancing tremor Advanced cardiac, renal, hepatic or other disabling conditions making patient physical unable to participate in examination and receiving the intervention Use of new medications with potential effect on tremor

Age
 From **18 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
 Target sample size: **30**
 Actual sample size reached: **23**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Block randomization using sealed envelopes

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Participants: by use of sham procedure Outcome assessor: an investigator blinded to the type of intervention assessed outcome and another investigator performed data entry and analysis

Placebo
 Used

Assignment

Crossover
Other design features

Secondary Ids

1

Registry name
 ClinicalTrials.gov

Secondary trial Id
 NCT02704793

Registration date
 2016-03-10, 1394/12/20

Ethics committees

1

Ethics committee
Name of ethics committee
 Research Ethics Committee of Mashhad University of Medical Sciences

Street address
 Sakhteman-e-Ghoreishi, Daneshgah St., Research Ethics Committee

City
 Mashhad

Province
 Razavi Khorasan

Postal code
 91357345

Approval date
 2015-10-07, 1394/07/15

Ethics committee reference number
 ir.mums.sm.rec.1394.353

Health conditions studied

1

Description of health condition studied
 Essential Tremor

ICD-10 code
 G25.0

ICD-10 code description
 Essential Tremor

Primary outcomes

1

Description
 Tremor severity

Timepoint
 At the baseline and on days 5, 12, 30 after each real or sham treatment session

Method of measurement
 Fahn-Tolosa-Marin scale

Secondary outcomes

empty

Intervention groups

1

Description

Sham treatment (electrical stimulation of less than 3 milli amperes) using a small device located on the coil, invisible to the patient, providing 900 pulses on each cerebellar hemisphere daily for 5 days.

Category

Placebo

2

Description

Bilateral Cerebellar rTMS using the butterfly coil providing 900 pulses on each cerebellar hemispheres daily for 5 days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Neurology, Ghaem Hospital

Full name of responsible person

Nahid Olfati

Street address

Department of Neurology, Ghaem hospital, Ahmadabad st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice Chancellor of Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Research Vice Chancellor of Mashhad 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

Department of Neurology, Mashhad University of Medical Sciences

Full name of responsible person

Nahid Olfati

Position

Neurologist

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data file is available along with the submitted manuscript

When the data will become available and for how long

Anonymized data is available open access

To whom data/document is available

open access

Under which criteria data/document could be used

Academics might use data provided that funding sources are cited and contacted

From where data/document is obtainable

contact publisher of our final manuscript

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

doi:10.1016/j.brs.2019.10.003 or contact corresponding author shoeibia@mums.ac.ir

Comments

Person responsible for updating data

Contact

Name of organization / entity

Department of Neurology, Mashhad University of Medical Sciences

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Position

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