

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Efficacy of Repetitive Transcranial Magnetic Stimulation to Reduce Muscle Spasticity in Patients with Traumatic Brain Injury

Protocol summary

Study aim

Reduction of complications in brain trauma patients using RTMS technique and evaluation of RTMS effect on spasticity of patients

Design

40 susceptible patients suffering from traumatic brain injury have been divided into intervention and control groups. A blind, parallel, randomized strain

Settings and conduct

A sample of 40 patients referring to the Rehabilitation Center of Shahid Rajaei Hospital in 2018-2019, who are suffering from spastic brain injury due to trauma, are selected. The motor cortex is stimulated by 8-shaped coil with the magnetic stimulation pattern. Magnetic stimulation is applied with the following characteristics: Frequency: 1 Hz / Number of pulses: 1500 / Severity: 90% of the motor threshold. Each person receives transcranial magnetic stimulation (TMS) per day for 10 days. Prior to intervention, muscle spasticity, Muscle strength and daily activity levels are evaluated and the same evaluations are performed again at the end of the intervention. The patient and the examiner are unaware of the intervention being performed or not performed and device kept off in the control group by the technician

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18-75, non-history of ischemic stroke or hemorrhagic and multiple sclerosis, muscle spasticity with grades 3 and 4, strength of 3rd grade. No dryness and joint adhesion. Non-major fractures, no history of skull surgery in the past. No history of cardiac arrhythmia. Exclusion criteria: history of cerebral aneurysm or seizure, history of metal or clips implants, unstable vital signs, chronic pain

Intervention groups

The patients are randomly assigned to both case and control groups. The group under RTMS and the control group are studied by the coil off of the sham stimulation device.

Main outcome variables

Muscle tone, muscle strength, daily activity levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171215037872N1**

Registration date: **2019-07-13, 1398/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-13, 1398/04/22**

Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

Azin Hasanzadeh Salmasi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Repetitive Transcranial Magnetic Stimulation to Reduce Muscle Spasticity in Patients with Traumatic Brain Injury

Public title

Efficacy of Repetitive Transcranial Magnetic Stimulation to Reduce Muscle Spasticity

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 and under 75 years presence of muscle spasticity at grades 3 and 4 in at least one of the muscle compartments With muscle_ power grading over 3

Exclusion criteria:

History of ischemic or hemorrhage stroke and multiple sclerosis Existence of joint dryness and adhesion Major fractures and history of cerebral cranial surgeries in the past positive history of cardiac arrhythmias positive history of brain aneurysm or seizure (focal or generalized) history of surgery involving metal or clips implants unstable Vital signs Chronic Pain

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment method In this study, the method of the permutation block will be such that A represents the person receiving the intervention and B represents the person who does not receive the intervention. This method, taking into account the six-membered blocks so that the total number of possible quadrupole permutations is equal to 4, includes: AABB, ABAB, BABA, BBAA. Then, with Using the random numbers table and assigning the code from 0 to 9 to each permutation, (randomized list of 60) (considering the drop in patients from the study), which includes 15 blocks of 4 ($60 \div 4 = 15$ total number of samples) And the order of assignment of each method to each of the participating samples is determined. For example: (ABAB Code 0, AABB Code 1, BABA Code 2, BBAA Code 3 to 9) Then, using the random numbers table, the starting point is selected randomly and 15 randomly selected (row or column) is selected and the assigned permutation is written to each number. (The order of placing permutations next to each other is left to right respectively) and how all 60 people will be assigned to

the two groups A and B

Blinding (investigator's opinion)

Double blinded

Blinding description

The control group was studied by the coil off of the sham stimulation device. The patient's examiner who evaluates spasticity is not aware of the lack or existence of the device .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Fifth Floor, Central Building of Shiraz University, Jomhuory Boulevard

City

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Province

Fars

Postal code

71946-84471

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.SUMS.MED.REC.1396.82

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

Spasticity in traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

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

muscle tone

Timepoint

The beginning of the study, before and after each intervention, one month after the end of the interventions

Method of measurement

Data collection is done through the Modified Ashworths Scale to evaluate the muscle tone that points to 0 to 4 for the patient's examination.

2

Description

power of muscle

Timepoint

The beginning of the study, before and after each intervention, one month after the end of the interventions

Method of measurement

Using the MRC Score based on the range of patient's movement, the score is 0-5.

3

Description

Activity of daily living

Timepoint

The beginning of the study, before and after each intervention, one month after the end of the interventions

Method of measurement

The score for Barthel's score is 0-100 based on the patient's daily activity

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes 20 traumatic brain injury patients who are eligible for the study and randomly selected. The motor cortex is determined by a coil of the 8th form of magnetic stimulation. Prior to that, the threshold of motion of the intervertebral muscles of the back of the other side is determined. The lowest single pulse intensity is tms with a stimulated motor potential of 50 millivolts, determined by EMG. The following magnetic stimulation is applied as follows: Frequency: 1 Hz / pulse number: 1500 / intensity: 90% of the motor threshold Each person receives a TMS meeting for 10 days a day.

Category

Rehabilitation

2

Description

Control group: Twenty traumatic brain injury patients who were eligible for the study were randomly selected. The control group was studied by the coil off of the sham stimulation study.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Shiraz Hospital

Full name of responsible person

Sharareh Roshanzamir

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16th floor,Gole narges building, Shahid Goodarzi street,Shahid Rajaee Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Seventh Floor-near Red Crescent - Central Building of Shiraz University of Medical Sciences-Zand Avenue - Shiraz

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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

Shiraz 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

+98 71 3230 5410

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sharareh.roshanzamir@gmail.com

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sharareh Roshanzamir

Position

Non-faculty specialist

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Latest degree

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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