Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Rajaee Hospital in 2018-2019, who are suffering from spastic brain injury due to truma, 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 * 4 * 60 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
Shiraz

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 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
Street address
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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71345-1978
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
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

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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16th floor,Gole narges building, Shahid Goodarzi street,Shahid Rajaee Blvd.
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Latest degree
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Physical Medicine
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Person responsible for updating data

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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