

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Investigating the effect of rTMS therapy concomitant with rehabilitation on motor deficit of upper extremities of TBI patients in comparison to rehabilitation alone

Protocol summary

Summary

this project is about treatment of TBI patients with combination of rTMS and rehabilitation and rehabilitation alone and investigating the effect of these treatments on upper extremity disability and hand grip, we have 2 groups and each group contains 7 patients who were selected randomized, the first group gets rehabilitation plus not real rTMS and the second group gets rehabilitation and real rTMS. Before starting the treatments, exactly after that and then 3 weeks later we evaluate and compare the results of grip and questionnaire. This project is double blinded for patients and doctors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011932053N1**

Registration date: **2017-03-28, 1396/01/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-28, 1396/01/08

Registrant information

Name

Raziyeh Shiravani

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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shirvanira@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-09-01, 1395/06/11

Expected recruitment end date

2016-12-03, 1395/09/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of rTMS therapy concomitant with rehabilitation on motor deficit of upper extremities of TBI patients in comparison to rehabilitation alone

Public title

Investigating the effect of rehabilitation with and without rTMS (repetitive transcranial magnetic stimulation) on upper extremity motor deficit of traumatic brain injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: motor deficit at least in one upper extremity, passes a month from TBI, muscle power less than or equal to 4, cooperation of the patient in therapeutic sessions, contusion of motor cortex in CT Scan Exclusion criteria: musculoskeletal injury, bone fracture, co-existing neurological diseases like MS, limited mobility not due to traumatic brain injury, history of epilepsy-arrhythmia in family or himself, having implant, pacemaker or clips in brain

Age

From **23 years** old to **52 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Shiraz University of Medical Sciences

Street address

Building of the Central University of Medical Sciences, across the Palastinian street, Zand Street, Shiraz

City

Shiraz

Postal code

7134814336

Approval date

2017-02-05, 1395/11/17

Ethics committee reference number

IR.SUMS.REC.1395.179

Health conditions studied

1

Description of health condition studied

brain injury

ICD-10 code

S06.3, S06

ICD-10 code description

focal brain injury,Other intracranial injuries

2

Description of health condition studied

motor deficit

ICD-10 code

v01-x59

ICD-10 code description

accidents

Primary outcomes

1

Description

brain injury

Timepoint

before treatment

Method of measurement

sign,symptoms,CT scan

2

Description

motor deficit

Timepoint

before tretment, at the end, 3 weeks later

Method of measurement

dinamometer

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: treatment with rTMS with high frequency(10HZ),20 minutes for each 10 sessions (3 sessions in a week) and rehabilitation(physiotherapy and excercise) for 10 sessions and each sessions has 40 minutes.

Category

Treatment - Other

2

Description

control group: rehabilitation (physiotherapy and excercise) for 10 sessions and each sessions has 40 minutes and false rTMS 20 minutes for each 10 sessions (3 sessions in a week)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Sharareh Roshanzamir

Street address

Rajai Hospital, not far from the Niyayesh boulevard, Chamran boulevard, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Sharareh Roshanzamir

Street address

Building of the Central University of Medical Sciences, across the Palestinian street, Zand Street, Shiraz

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Sharareh Roshanzamir

Position

assistant professor, specialist of physical medicine and rehabilitation

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

