

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3635 7477

##### Email address

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

**Other areas of specialty/work****Street address**

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

**City**

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**Postal code****Phone**

+98 71 3231 9040

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sharareh.roshanzamir@gmail.com

**Web page address**

## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

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Sharareh Roshanzamir

**Position**

Assistant professor, specialist in physical medicine & rehabilitation

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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## 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*

