

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of r-TMS on post-stroke headaches

Protocol summary

Study aim

Determination of the effect of repeated cerebral stimulation on headache after stroke in patients referred to Rajaei Hospital

Design

During treatment, patients usually have to sit on a special chair designed for this purpose, the chin and forehead of the patient will be placed in a special frame to be fixed. This frame has been designed to prevent any unwanted movement of the patient during treatment. The holder holder is required for treatment, because the stimulus device does not touch the patient's head, it is about a few centimeters above the patient's head. During magnetism of the head, the magnetic coil should be carefully positioned at the right position, right above the patient's head, and, as a matter of fact, only the area where the doctor is intended to be treated. When the patient was ready, the physician switched on the device to turn the magnetic screw wires into a pole, and a short magnetic pulse was generated (the intervention group) Like the intervention group but the device is off

Settings and conduct

Rajaei Hospital

Participants/Inclusion and exclusion criteria

Includes all CVA and headache patients Each patient rate for 20 minutes to 10 sessions RTMS LOW FREQUENCY be placed on the area of the brain M1

Intervention groups

Intervention group: This treatment takes up to 6 months for each patient for 20 minutes for 10 sessions of RTQM FREQ in the M1 brain area. In the control group: Like the intervention group but But the device is off

Main outcome variables

The headache after stroke

General information

Reason for update

Acronym

r-TMS

IRCT registration information

IRCT registration number: **IRCT20181005041236N1**

Registration date: **2019-01-12, 1397/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-12, 1397/10/22**

Update count: **0**

Registration date

2019-01-12, 1397/10/22

Registrant information

Name

Shirinolsadat Hashemi rafsanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8807 6431

Email address

hashemirsh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of r-TMS on post-stroke headaches

Public title

r-TMS on post-stroke headaches

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Includes all patients with CVA with headache

Exclusion criteria:
Unrelated patients with CVA. People with headache other than CVA such as migraine and tension headaches, people with malignant diseases Non-participation in the study

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: 48

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method was done by using a random number table. First, all participants were assigned a code from 1 to 48. Next, a random number was selected from the table, and the corresponding code for the patients in one of the two groups was equally divide

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient and the person who evaluates or collects the data is not known to the group Due to the fact that in both groups the process is similar, the patient does not know the treatment A person who does the evaluation process and record the results of the method is not implemented Only the investigator and the technician who performs the treatment have full knowledge of the treatment The patient is told to have one of two methods applied

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

school of medicine - shiraz university of medical science

Street address

Zand Blvd.

City

shiraz
Province
Fars
Postal code
۷۱۳۳۶ - ۷۱۳۴۸

Approval date

2018-08-06, 1397/05/15

Ethics committee reference number

IR.SUMS.MED.REC.1397.204

Health conditions studied

1

Description of health condition studied

r-TMS on post-stroke headaches

ICD-10 code

D77*

ICD-10 code description

Other disorders of blood and blood-forming organs in diseases classified elsewhere

Primary outcomes

1

Description

Determination of the mean headache after stroke in the study group before and after the procedure rtms

Timepoint

For each patient for 20 minutes for 10 sessions up to 6 months

Method of measurement

Based on the VAS scale for pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for each patient for 20 minutes for 10 sessions of RTMS FREQ in the M1 region of the brain, this treatment lasts up to 6. In the intervention group, the chin and forehead of the patient will be placed in a special frame and, during the magnetic stimulation of the head, the magnetic coil will be adjusted precisely in the appropriate position, right above the patient's head. When the patient is ready, the physician will turn on the device until magnetic coils Changing the pole and producing a short magnetic pulsemonths

Category

Treatment - Devices

2

Description

Control group: This treatment lasts up to 6 months for each patient for 20 minutes for 10 sessions of RTMS

FREQ in the M1 region of the brain. But the device is off

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajai Hospital in Shiraz

Full name of responsible person

Dr Sharareh Roshanzamir

Street address

Shiraz, Zand Avenue, Opposite Street, central Building
of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3230 5645

Email

sharareh.roshanzamir@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Aghaye Dr Mohamad Javad Ashraf

Street address

Karimkhanzand Boulevard

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3235 1087

Email

sharareh.roshanzamir@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

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

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Karim khan Zand Boulevard

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3235 1087

Email

sharareh.roshanzamir@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shareh Roshanzamir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Karimkhan zand Boulevard

City

shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

Sharareh.roshanzamir@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sharareh Roshanzamir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Karimkhan zand Boulevard, ,Opposite Street, central
Building of Shiraz University of Medical Sciences

City

shiraz

Province

Fars

Postal code

713484419

Phone

+98 71 3235 1087

Email

sharareh.roshanzair@gmail.com

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

Yes - There is 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

Title and more details about the data/document

Information will be provided in general and with statistical indicators

When the data will become available and for how long

Start collecting data in 1397

To whom data/document is available

If necessary, researchers working at the university

Under which criteria data/document could be used

If you submit a valid proposal

From where data/document is obtainable

Sharareh.roshanzamir@gmail.com apply to the e-mail address

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

After applying for ten days

Comments