Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Rajaee 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 butthe device is off

Settings and conduct
Rajaee 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)

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+98 21 8807 6431

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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

۱۴۳۳۶ - 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

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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

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Karimkhanzand Boulevard

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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

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Person responsible for scientific inquiries

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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
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