

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of treatment with Trans cranial direct current stimulation in comparison with Repetitive Trans cranial Magnetic Stimulation in improving pain, anxiety, depression and quality of life in patients with migraine

Protocol summary

Study aim

Evaluation of the effectiveness of treatment with Transcranial direct current stimulation in comparison with Repetitive Transcranial Magnetic Stimulation in improving pain, anxiety, depression and quality of life in patients with migraine

Design

Clinical trial with two parallel groups of intervention, without blinding, randomized, phase 2 on 72 patients

Settings and conduct

In this randomized clinical trial study without blindness, 72 migraine patients candidate for TDCS and RTMS referred to Kashani Hospital in Isfahan will be divided into two groups. One group will be treated with TDCS and the other group will be treated with RTMS. Then pain intensity, depression, anxiety and quality of life score will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion: Patients with migraine and a history of migraine attacks in the past year. Not inclusion: Any Contraindications for TDCS and RTMS, history of any brain stimulation and any major Psychiatric disorders

Intervention groups

TDCS intervention group: electrical stimulation with intensity of 2 mA will be delivered in the Dorsolateral Prefrontal cortex, in twelve sessions, every other day. RTMS intervention group: Magnetic stimulation with a frequency of 10 Hz, 600 pulses in 10 trains for 412 seconds and 70% stimulation threshold of each person will be delivered in the Dorsolateral Prefrontal cortex, in three sessions every other day.

Main outcome variables

Pain intensity; Depression score; Anxiety score; Quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190404043159N4**

Registration date: **2021-10-09, 1400/07/17**

Registration timing: **prospective**

Last update: **2021-10-09, 1400/07/17**

Update count: **0**

Registration date

2021-10-09, 1400/07/17

Registrant information

Name

Mohammad Reza Sharbafchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2475

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Evaluation of the effectiveness of treatment with Trans cranial direct current stimulation in comparison with Repetitive Trans cranial Magnetic Stimulation in improving pain, anxiety, depression and quality of life in patients with migraine
Public title	Comparison of the effect of TDCS and RTMS in the treatment of migraine
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	All 18 to 60 years old migraine patients with the code (ICHS-II 1.2.1) according to the International Classification of Headache Disorders (2004) and with a history of migraine attacks (of any severity) during a recent year that is confirmed by a neurologist. Conscious consent to participate in the study Have a minimum literacy
Exclusion criteria:	A serious suicide plan or thoughts Pregnancy or Breastfeeding Substance abuse A history of seizures or any neurological disease (other than Migraine) Having a Pacemaker or any metal Implants in the upper limbs or head and neck History of any brain stimulation such as ECT(Electroconvulsive therapy) 7. History of taking antidepressants and anti-anxiety drugs from two months before entering the study Depressive, Bipolar, or Psychotic disorders based on DSM-V (Diagnostic and Statistical Manual of Mental Disorders) Criteria during examination by a Psychiatrist and Psychiatric Assistant
Age	From 18 years old to 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 72
Randomization (investigator's opinion)	Randomized
Randomization description	The double random blocks method is used for randomization. In this way, both eligible patients are placed in a block and are arranged according to the national code, and a table of random numbers is used to determine the placement of patients in groups A or B. Numbers 0 to 4 will be in group A and numbers 5 to 9 will be in group B. Then, by tossing a coin, treatment method A is assigned to one method and B to the other treatment method.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used

Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Esfahan university of Medical sciences
Street address	No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan
City	Isfahan
Province	Isfahan
Postal code	
Approval date	2021-08-02, 1400/05/11
Ethics committee reference number	IR.MUI.MED.REC.1400511

Health conditions studied

1	
Description of health condition studied	Migraine
ICD-10 code	G43
ICD-10 code description	Migraine

Primary outcomes

1	
Description	Pain intensity based on Visual Analogue Scale (VAS)
Timepoint	At the beginning of the study and one month after the intervention
Method of measurement	Pain intensity based on Visual Analogue Scale (VAS)
2	
Description	Depression score
Timepoint	At the beginning of the study and one month after the intervention
Method of measurement	Based on the Hospital Anxiety and Depression Scale (HADS)

3

Description

Anxiety score

Timepoint

At the beginning of the study and one month after the intervention

Method of measurement

Based on the Hospital Anxiety and Depression Scale (HADS)

4

Description

Quality of life score

Timepoint

At the beginning of the study and one month after the intervention

Method of measurement

Based on the Headache Impact Test (HIT) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with migraine will be treated with electrical stimulation by the TDCS method with a intensity of 2 mA in the Dorsolateral Prefrontal cortex, in twelve sessions, every other day.

Category

Treatment - Devices

2

Description

Intervention group: Patients with migraine treated with magnetic stimulation by RTMS method, with a frequency of 10 Hz, 600 pulses in 10 trains for 412 seconds and 70% of the stimulation threshold of each person in the Dorsolateral Prefrontal cortex, in three sessions, every other day.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospi al

Full name of responsible person

Mohammad Reza Sharbafchi

Street address

Kashani St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Reza Sharbafchi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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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