Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+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
Isfehan

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 Hospial
Full name of responsible person
Mohammad Reza Sharbafchi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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 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
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