Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of prefrontal-occipital transcranial direct current stimulation for refractory chronic migraine

Protocol summary

Study aim
To Investigate the Effect of Transcranial Direct Current Stimulation in Patients with chronic migraine referred to the Neurology clinic, Sina Hospital, Tehran

Design
tDCS is administered by a trained operator using a 2mA current. Electrodes are placed according to the 10–20 EEG system, with the cathode at Oz and the anode at the right DLPFC (F4). Each session lasts 20 minutes and is performed at a similar time of day. Treatment includes three consecutive sessions in week 1, three in week 2, followed by weekly sessions until session 12.

Settings and conduct
Sina Hospital Headache Interventional Center

Participants/Inclusion and exclusion criteria
Patients aged 18 to 60 years with chronic migraine, with or without MOH, presenting to the Neurology Clinic of Sina Hospital. Lack of response to at least three types of preventive migraine medications, with at least three months having passed since the initiation of the last preventive treatment and the treatment not having provided adequate efficacy. The patient should also have no intention of changing the dose or discontinuing the medication until the end of the follow-up period. Exclusion criteria: • Patients with uncontrolled hypertension • Patients with uncontrolled systemic diseases (uncontrolled hypothyroidism, renal or hepatic disorders) • Previous use of tDCS for headache control • Patients with a history of substance abuse • Patients with seizures • Pregnant or breastfeeding patients • Patients with a prior pacemaker or metallic devices in the scalp • History of botulinum toxin injection within the past six months • History of brain surgery or brain tumor • History of any other serious neurological disorder besides migraine

Intervention groups
tDCS for patients with chronic migraine with or without MOH

Main outcome variables
Frequency, intensity, and duration of headache Analgesic consumption Severity of anxiety and depressive disorders

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140624018213N2**
Registration date: **2026-06-17, 1405/03/27**
Registration timing: **retrospective**

Last update: **2026-06-17, 1405/03/27**
Update count: **0**

Registration date
2026-06-17, 1405/03/27

Registrant information

Name
Mansoureh Togha

Name of organization / entity
Tehran University of medical sciences

Country
Iran (Islamic Republic of)

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+98 21 6634 8500

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toghae@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
2023-05-22, 1402/03/01

Actual recruitment end date
2024-01-21, 1402/11/01
Trial completion date
2024-03-20, 1403/01/01

Scientific title
Efficacy of prefrontal-occipital transcranial direct current stimulation for refractory chronic migraine

Public title
Investigation of the Effect of Transcranial Direct Current Stimulation on Headache in Patients with Chronic Migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Chronic Migraine with/without MOH 18- 60 years old Visit to Sina Hospital Headache Clinic Inadequate response to at least three preventive migraine medications, with at least three months having passed since the initiation of the most recent treatment. No intention to change the dose or discontinue the medication until the end of the follow-up period.
Exclusion criteria:
Patients with uncontrolled hypertension Patients with uncontrolled systemic disease (hypothyroidism, uncontrolled renal and hepatic impairment) Previous use of tDCS for headache control Patients with a history of substance abuse Patients with seizures Patients during pregnancy or lactation Patients with a previous pacemaker or metal devices in the scalp History of botulinum toxin injection in the past six months History of brain surgery or brain tumor History of other serious neurological problem other than migraine headache
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Neuroscience Institute
Street address
Sima-ye-Iran
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2023-06-11, 1402/03/21
Ethics committee reference number
IR.TUMS.NI.REC.1402.008

Health conditions studied

1

Description of health condition studied
Chronic Migraine
ICD-10 code
G43.909
ICD-10 code description
Migraine, unspecified, not intractable, without status migrainosus

Primary outcomes

1

Description
Frequency of headache
Timepoint
Before the intervention
Method of measurement
Headache Questionnaire

2

Description
Intensity of headache
Timepoint
Before the intervention
Method of measurement
VAS Score

3

Description
Duration of headache
Timepoint
Before the intervention
Method of measurement
Headache Questionnaire

4

Description
Analgesic consumption
Timepoint
Before the intervention
Method of measurement
Headache Questionnaire

5

Description
Severity of anxiety and depressive disorders
Timepoint
Before the intervention
Method of measurement
Ḍass21 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
tDCS is administered by a trained operator at 2 mA. Electrodes are placed according to the 10–20 EEG system, with the cathode at Oz and the anode at the right DLPFC (F4). Each session lasts 20 minutes and is performed at a similar time of day. Treatment includes three consecutive sessions in week 1, three in week 2, followed by weekly sessions until session 12.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital Headache Clinic
Full name of responsible person
Mansoureh Togha
Street address
Imam Khomeini
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1136746911
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toghae@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
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Qods
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Province
Tehran
Postal code
141765383761
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mansoureh Togha
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Neurology
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Person responsible for scientific inquiries

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Position
Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Patients' data will be kept confidential by the corresponding author and, upon request of the journal editor, may be temporarily and selectively shared with the editor solely for verification of the findings.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable