

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of transcranial direct current stimulation with three approaches, anodal occipital cortex, cathodic occipital cortex and sham on clinical outcomes in patients with chronic migraine

Protocol summary

Study aim

Comparing the effectiveness of transcranial direct current stimulation with three approaches: anodal occipital cortex, cathodal occipital cortex and sham on clinical outcomes in patients with chronic migraine

Design

A clinical trial with a control group (sham), with parallel groups, double-blind, randomized, on 114 patients. The website <https://www.sealedenvelope.com> was used for randomization with an equal allocation ratio in each group by a non-involved person.

Settings and conduct

114 patients with chronic migraine resistant to routine treatment who referred to the pain clinic of Velayat Hospital will be included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with chronic migraines with indications for prophylactic treatment in the age group of 18 to 65 years, resistant to drug treatments and those who experience frequent migraine attacks and take painkillers. Exclusion criteria: history of neurological diseases, history of mental disorder and use of antipsychotic and antidepressant drugs, drug abuse during study or in the past few months, episodic migraine, history of treatment with tDCS or other brain stimulation techniques, use voltage-dependent sodium and calcium channel blockers or the patient's lack of consent to continue participating in the study.

Intervention groups

Intervention group: occipital cortex anodal tDCS group and occipital cortex cathodal tDCS group. Control group: sham stimulation group (sham)

Main outcome variables

Number of migraine days per month, attack duration, pain intensity, frequency of taking painkillers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100501003844N5**

Registration date: **2023-02-15, 1401/11/26**

Registration timing: **prospective**

Last update: **2023-02-15, 1401/11/26**

Update count: **0**

Registration date

2023-02-15, 1401/11/26

Registrant information

Name

Cyrus Emir Alavi

Name of organization / entity

Guilan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1321 1245

Email address

cyrusemiralavi@irimc.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty		the envelopes and the random sequencing of the allocation will be done by a person not involved in the research.	
Scientific title		Placebo	
Comparison of the effectiveness of transcranial direct current stimulation with three approaches, anodal occipital cortex, cathodic occipital cortex and sham on clinical outcomes in patients with chronic migraine		Not used	
Public title		Assignment	
The effectiveness of transcranial direct current stimulation on the clinical outcomes of chronic migraine patients		Parallel	
Purpose		Other design features	
Treatment		Secondary Ids	
Inclusion/Exclusion criteria		empty	
Inclusion criteria:		Ethics committees	
Patients with chronic migraine Resistant to drug treatments Those who experience frequent migraine attacks Experienced at least 4 attacks per month or 8 days of migraine attacks per month		<u>1</u>	
Exclusion criteria:		Ethics committee	
History of neurological diseases History of mental disorder and use of antipsychotic and antidepressant drugs History of treatment with tDCS or other brain stimulation techniques Taking drugs that block voltage-dependent sodium and calcium channels Failure of the patient to continue participating in the study		Name of ethics committee	
Age		Ethics committee of Guilan University of Medical Sciences	
From 18 years old to 65 years old		Street address	
Gender		University Research and Technology Vice-Chancellor- in front of 17 Shahrivar Hospital- Shahid Siadati St. - Namjo St.	
Both		City	
Phase		Rasht	
N/A		Province	
Groups that have been masked		Guilan	
• Participant • Outcome assessor		Postal code	
Sample size		41937-13194	
Target sample size: 144		Approval date	
Randomization (investigator's opinion)		2022-07-13, 1401/04/22	
Randomized		Ethics committee reference number	
Randomization description		IR.GUMS.REC.1401.225	
In this clinical trial study, 114 patients suffering from chronic migraine and resistant to prescribed drugs, who referred to the pain clinic of Velayat Hospital, were randomly selected using the random block method using blocks of 6 and using From the website https://www.sealedenvelope.com , they will be assigned to three groups A, B, C as follows, with an equal allocation ratio in each group by a person not involved in the research. 1) anodal tDCS of the occipital cortex, anode electrode on the occipital cortex of the dominant side of pain and cathode on the chin, 2) cathodal tDCS of the occipital cortex, cathode electrode on the occipital cortex of the dominant side of pain and anode electrode on the chin of the opposite side, 3) stimulation group fake		Health conditions studied	
Blinding (investigator's opinion)		<u>1</u>	
Double blinded		Description of health condition studied	
Blinding description		Migraine patients	
To hide the allocation of drugs, they will be placed in a sealed, numbered matte envelope. The preparation of		ICD-10 code	
		G43	
		ICD-10 code description	
		Migraine	
		Primary outcomes	
		<u>1</u>	
		Description	
		Number of migraine days per month, pain intensity, frequency of taking painkillers	
		Timepoint	
		Before the start of the intervention, after the last session of the intervention and two months after	
		Method of measurement	
		Based on questions from the patient	

Secondary outcomes

1

Description

Intensity of pain

Timepoint

Before the start of the intervention, after the last session of the intervention and two months after

Method of measurement

Using Visual Analogue Scale(VAS), according to patient report

Intervention groups

1

Description

Intervention group: Occipital cortex anodal tDCS group, the anode electrode is placed on the occipital cortex on the dominant side of the pain and the cathode on the chin on the opposite side.

Category

Treatment - Devices

2

Description

Intervention group: Cathodal tDCS group of the occipital cortex, the cathode electrode is placed on the occipital cortex of the dominant side of the pain and the anode electrode is placed on the chin of the opposite side.

Category

Treatment - Devices

3

Description

Control group: The fake stimulation group (sham) also has electrodes with the same arrangement (occipital cortex and chin) and for the duration of the experimental group, with the difference that the electric current will be cut off after 30 seconds.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pain Clinic of Velayat Hospital

Full name of responsible person

Cyrus Emir Alavi

Street address

Porsina Crossroads, Hafez Street

City

Rasht

Province

Guilan

Postal code

41937-13194

Phone

+98 911 131 7398

Email

Cyrusemiralavi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Naqipour

Street address

Shahid Siyadati St, Namjo St.

City

Rasht

Province

Guilan

Postal code

41937-13194

Phone

+98 13 3333 6394

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Cyrus Amir Alavi

Position

Associate Professor of Pain Anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Velayat Educational and Medical Center, Namjo St.

City

Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8814
Email
cyrusemiralavi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Cyrus Amir Alavi
Position
Associate Professor of Pain Anesthesiology
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Velayat Educational and Medical Center, Namjo St.
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 911 131 7398
Email
Cyrusemiralavi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Cyrus Emir Alavi
Position
Associate Professor of Pain Anesthesiology
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Velayat Educational and Medical Center, Namjo St.
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8814
Email
cyrusemiralavi@yahoo.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

No - There is not 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