Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Influence of tDCS and tACS Noninvasive Brain Stimulation Treatments on Pain Perception and Severity of Symptoms in Patients with Migraine

Protocol summary

Study aim
Comparing the effect of tDCS and tACS treatment on the average score of pain perception and severity of migraine symptoms questionnaires, the average duration, intensity, and number of migraine attacks per unit of time (month)

Design
Controlled, parallel-group, single-blind (participants), randomized, phase 3 clinical trial on 45 patients, using random numbers in a randomization calculator

Settings and conduct
Zahedan; Baharan Psychiatric Hospital 10 min. relaxation at the beginning of each Sess. Stim. while sitting on a chair Closed eyelids No activity Quiet place

Participants/Inclusion and exclusion criteria
People with migraine diagnoses who are referred by public or private pain clinics, internal neurologists, and neurologists criteria: adult, Migraine onset age under 50, Having at least primary school education, No history of hospitalization in a psychiatric hospital, Not suffering from severe depression/anxiety, No history of cardiovascular diseases, No addiction to alcohol or other substances, Absence of other forms of headache, Absence of neurological disorders or cerebrovascular diseases, No previous history of receiving any other type of brain stem; No new medication starting (in case of the first visit) or no changing of the prescribed medication from 2 weeks before the start of the intervention to two weeks after the end of the intervention.

Intervention groups
Intervention 1: Anodal tDCS on the M1 region, an intensity of 2mA for 20 minutes, 12 Sess. (3 Sess. per week), cathode on the left shoulder. Intervention 2: tACS on the M1 region, the intensity of 2mA, 10 Hz freq. for 20 minutes, 12 sessions (3 sessions per week), cathode on the left shoulder. Control group: Only completing the questionnaires with an interval of 1 month.

Main outcome variables
Questionnaires scores; duration, intensity, and number of migraine attacks per unit of time (month)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221230056984N1**
Registration date: **2023-06-08, 1402/03/18**
Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**
Update count: **0**

Registration date
2023-06-08, 1402/03/18

Registrant information
Name
Bahare Aryan
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-06-20, 1402/03/30
Expected recruitment end date
2023-09-06, 1402/06/15
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Influence of tDCS and tACS Noninvasive Brain Stimulation Treatments on Pain Perception and Severity of Symptoms in Patients with Migraine

Public title
Comparison of the Influence of tDCS and tACS Treatment on Pain Perception and Severity of Symptoms in Patients with Migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from migraine based on the diagnosis of one of internal neurologists, neurologists and pain specialists
Exclusion criteria:
Having a history of hospitalization in a psychiatric hospital Suffering from severe depression or anxiety Having a history of cardiovascular diseases (such as high blood pressure) Addiction to alcohol or other substances Suffering from other forms of headache, including tension headaches, sinusitis, and headaches caused by drug abuse Suffering from neurological disorders such as epilepsy, stroke, head and neck trauma, and cerebrovascular diseases Starting the use of medication (in case of first visit) or changing the prescribed medication, from two weeks before the intervention to two weeks after the end of the intervention. Previous history of receiving any other brain stimulation Not having at least primary education
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Clients receiving a diagnosis of migraine from internal neurologists, neurologists, or pain specialists will be included in the study in the form of available sampling. If they meet the before randomization inclusion criteria we generate random numbers from 1 to 99 using a calculator for each client. If the random number is between 1 and 33, the person will be in the tDCS group, if the random number is between 34 and 66, the person will be in the tACS group, and if the random number is between 67 and 99, the person will be in the control group. If each group is completed, the range of numbers will be reduced by one-third (i.e. 1 to 66) and randomization will be done between the remaining two groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants in two intervention groups and one control group are not aware of which group they are in. The participants of the control group are asked to complete the questionnaires and wait for one month to participate in the research, and during this time they must comply with the condition of not changing the medication prescription. Once at the beginning and once at the end of the period, the questionnaires would get completed by them and after that, if they wish to continue participating in the research, the treatment will also apply for them.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Dr. Hesabi Square, Zahedan University of Medical Sciences compound, Administration building
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2023-04-30, 1402/02/10
Ethics committee reference number
IR.ZAUMS.REC.1402.072

Health conditions studied

1

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

Primary outcomes

1

Description
Pain Perception Score
Timepoint
Before starting and after the ending of intervention
Method of measurement
McGill Pain Perception Questionnaire (MPQ)

2

Description
Severity of migraine symptoms
Timepoint
Before starting and after the ending of intervention
Method of measurement
Ahvaz Migraine Questionnaire (AMQ)

3

Description
Migraine duration
Timepoint
Before starting and after the ending of intervention
Method of measurement
MIDAS Questionnaire

4

Description
Severity of migraine attack
Timepoint
Before starting and after the ending of intervention
Method of measurement
MIDAS Questionnaire

5

Description
Number of migraine attacks
Timepoint
Before starting and after the ending of intervention
Method of measurement
MIDAS Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group No.1: A Group that receives the tDCS protocol and comprises 15 people identified by A code. Anodal tDCS will be applied on their left lobe primary motor cortex (M1) with 2mA intensity for 12 consecutive sessions (three days per week), 20 minutes for each session.
Category
Treatment - Devices

2

Description
Intervention group No.2: A group that receives the tACS protocol and comprises 15 people identified with B code. Alternative stimulation will be applied on their left lobe primary motor cortex (M1) with 2mA intensity and 10Hz frequency for 12 sessions (three sessions per week), 20 minutes for each session.
Category
Treatment - Devices

3

Description
Control group: A group that comprises 15 people who don't receive any electrical stimulation. They will be told that they're on the waiting list for treatment. They would be asked to complete the questionnaires at the beginning and the end of a month and not to change their pharmaceutic prescription during this period. After the end of the waiting period, if they would like to continue the remedy process, they will receive the tDCS treatment protocol (because of its frequency in research).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Baharan Psychiatric Hospital
Full name of responsible person
Dr. Behzad Rigi Kote
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences

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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
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
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Position
Assistant Professor
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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