

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

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+98 51 3882 4512

Email address

bahare.ariyan@gmail.com

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

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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 pharmaceutical 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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Baharan Psychiatric Hospital, above of 54th Alley,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

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

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

Behzad Rigi Kote

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

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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