

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of tDCS and Sham tDCS for reduction of pain in patients with knee osteoarthritis

Protocol summary

Study aim

Aim is comparison of tDCS and Sham tDCS for reduction of pain in patients with knee osteoarthritis attending to Imam-Reza Hospital in 2019-2020

Design

Clinical trial with a control group with parallel groups, single-blind, randomized.

Settings and conduct

This study was conducted as a clinical trial in Imam Reza Hospital and in patients with knee osteoarthritis, this is a single-blind study in which patients will be blinded. This is in phase 4 and in this 54 patients with a block method are divided into two groups, 27 patients in first intervention group and receive tDCS, and 27 patients in second intervention group receiving Sham tDCS. Based on this, at first and three month after starting treatment, pain of patients will be assessed.

Participants/Inclusion and exclusion criteria

Patients with knee osteoarthritis, age between 20 to 70 years, pain over 6 months, VAS between 3 and 7 and Being able to express the intensity of pain will be included in study, also patients with a metal or device in the head, carbamazepine use in the last 6 months, drug addiction, alcohol consumption in the last 6 months, history of neurological diseases, history of neurosurgery and a history of severe depression will be excluded from study.

Intervention groups

In first group, stimulation will be performed using transcranial direct current stimulation (tDCS) for 5 sessions and for 5 consecutive days using a 35 cm 2 electrode with a current of 2 mA, each stimulation was performed for 20 minutes, and in another stimulation will be performed using Sham transcranial direct current stimulation (tDCS) for 5 sessions and for 5 consecutive days using a 35 cm 2 electrode with a current of 2 mA, each stimulation was performed for 30 seconds.

Main outcome variables

Pain of Knee Osteoarthritis

General information

Reason for update

The dates had been erroneously typed. Blinding statement had been written in the section Randomization. The randomization protocol had been written as "simple" (Now, it has been corrected into "block") We consider a placebo-sham control group in our study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191214045724N1**
Registration date: **2020-02-02, 1398/11/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-26, 1399/04/06**

Update count: **1**

Registration date

2020-02-02, 1398/11/13

Registrant information

Name

Bahar Mohebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 6637 3737

Email address

behar.moheb@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-27, 1398/11/07

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of tDCS and Sham tDCS for reduction of pain in patients with knee osteoarthritis

Public title

The effects of tDCS for pain relief of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 20 to 70 years Pain over 6 months VAS between 3 and 7 Being able to express the intensity of pain

Exclusion criteria:

A metal or device in the head Carbamazepine use in the last 6 months Drug addiction Alcohol consumption in the last 6 months History of neurological diseases History of Neurosurgery A history of severe depression

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

We use block randomization to ensure that the two groups are of the same size. Patients are randomized by blocked randomization of size two or four to the two groups of active or sham tDCS. Random numbers are generated in an independent statistical room using a computer. The units of randomization are individuals. There is no stratification in the randomization process.

Blinding (investigator's opinion)

Single blinded

Blinding description

Our study is a single-blind randomized trial. The participants will be unaware of the sham or active treatment they would receive throughout the study. The investigators and clinicians are not masked to the patients' group assignment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Aja University of Medical Sciences

Street address

Tehran, West Fatemi St., Etemadzadeh Avenue, Aja University of Medical Sciences

City

Arak

Province

Markazi

Postal code

1411718541

Approval date

2020-01-26, 1398/11/06

Ethics committee reference number

IR.AJAUMS.REC.1398.233

Health conditions studied**1****Description of health condition studied**

Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes**1****Description**

Pain of Knee Osteoarthritis

Timepoint

Instantly and 3 months after treatment

Method of measurement

Based on Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this group, stimulation was performed using transcranial direct current stimulation (tDCS) for 5 sessions and for 5 consecutive days using a 35 cm 2 electrode with a current of 2 mA, each stimulation was performed for 20 minutes.

Category

Rehabilitation

2

Description

Intervention group: In this group, stimulation was performed using Sham transcranial direct current stimulation (tDCS) for 5 sessions and for 5 consecutive days using a 35 cm 2 electrode with a current of 2 mA, each stimulation was performed for 30 seconds.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Bahare Mohebi

Street address

1411718541, Aja University of Medical Medical Sciences, Etemadzadeh Avenue, West Fatemi St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

behar.moheb@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mostafa Shahrezaee

Street address

1411718541, Aja Medical University, Etemadzadeh Avenue, West Fatemi St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

moshahrezayee@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Bahare Mohebi

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

1411718541, Aja University of Medical Sciences, Etemadzadeh Avenue, West Fatemi St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

behar.moheb@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Bahare Mohebi

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

1411718541, Aja University of Medical Sciences, Etemadzadeh Avenue, West Fatemi St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code
1411718541
Phone
+98 21 8609 6350
Email
behar.moheb@gmail.com

1411718541
Phone
+98 21 8609 6350
Email
behar.moheb@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Bahare Mohebi
Position
Resident of Physical Medicine and Rehabilitation
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
1411718541, Aja University of Medical Sciences,
Etemadzadeh Avenue, West Fatemi St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code

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