Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of tDCS and Sham tDCS in reducing pain and improving patient symptoms with shoulder tendinopathy

Protocol summary

Study aim
Comparison of pain, quality of life and functional scores between two groups

Design
After giving the necessary explanations, a signed written consent is obtained from the mentioned patients, and then they are treated with tDCS or control by block randomization method.

Settings and conduct
This double-blinded randomized clinical trial will be performed in Imam Reza Hospital in Tehran in 1400

Participants/Inclusion and exclusion criteria
Adult patients aged 20-65 years Pain for at least 6 weeks MRI-confirmed inflammation of the shoulder tendon Pregnancy and lactation Complete rupture of the rotator cuff The presence of active infection in the shoulder joint or surrounding tissues Coagulation disorders and the use of anticoagulants Cervical Radiculopathy Systemic rheumatic disorders Contraindications to tDCS Metal or electronic implants peace maker Pregnancy History of epilepsy

Intervention groups
The treatment is in 5 sessions using a 35 centimeter square electrode with a current of 2 milliamp. During intervention, the anode electrode is placed on the primary motor cortex on the opposite side of the most painful side and the cathode is placed on the opposite super-orbital, which of course has a protective sponge. In the tDCS group, the excitation rate reaches 2.5 milliamp from zero in the first 10 seconds, and this excitation lasts for 20 minutes and then reaches zero in 10 seconds. In the Sham group, the excitation rate reaches 2.5 milliamp from zero in the first 10 seconds, and this excitation lasts for 30 seconds and then reaches zero in 10 seconds. The duration of using active tDCS for intervention and control groups will be 20 minutes and 30 seconds respectively. However, the total time for electrode usage for patients in both groups will be equal to 20 minutes.

Main outcome variables
visual analogue scale (VAS) The Disabilities of the Arm, Shoulder and Hand (DASH) Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180416039324N3**
Registration date: **2021-09-02, 1400/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-02, 1400/06/11**
Update count: **0**

Registration date
2021-09-02, 1400/06/11

Registrant information

Name
Sirous Azizi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4382 3476

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-11, 1400/05/20

Expected recruitment end date
2022-02-09, 1400/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of tDCS and Sham tDCS in reducing pain and improving patient symptoms with shoulder tendinopathy

Public title
Comparison of tDCS and Sham tDCS in reducing pain and improving patient symptoms with shoulder tendinopathy referred to Imam Reza Hospital

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adult patients aged 20-65 years Pain at least 6 weeks MRI-confirmed shoulder tendonitis

Exclusion criteria:
Pregnancy and lactation Complete rotator cuff rupture History of tumor and malignancy Active infection in the shoulder joint or surrounding tissues Coagulation disorders and using anticoagulant drugs cervical radiculopathy Systemic rheumatic disorders Contraindications to tDCS such as metal or electronic implants, pacemakers, pregnancy and history of epilepsy

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to tDCS or Sham by block randomization in one of two groups. To randomly assign two groups with 20 participants in each group (40 patients in total), we use block randomization with different block sizes. The size of the blocks is a multiple of 2 and a divisor of 40 (2,4,8). Initially, the size of the blocks is randomly selected. Then for each block, different permutations are determined for the size of the equal group. Finally, one of the permutations is randomly selected. Random numbers are generated using a computer in an independent statistical unit.

Blinding (investigator's opinion)
Double blinded

Blinding description
The tDCS electrodes are placed at the predefined locations for the two groups in a similar manner for 20 minutes. In the tDCS group the active current time will be 20 minutes and in the SHAM group, it will be 30 seconds. Evaluators will also be unaware of the group allocations.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committees of AJA University of Medical Sciences

Street address
Imam Reza hospital, Etemad zade street, Fatemi street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1411718546

Approval date
2020-12-19, 1399/09/29

Ethics committee reference number
IR.AJAUMS.REC.1399.189

Health conditions studied

1

Description of health condition studied
shoulder tendinopathy

ICD-10 code
S46.0

ICD-10 code description
Injury of muscle(s) and tendon(s) of the rotator cuff of shoulder

Primary outcomes

1

Description
visual analogue scale

Timepoint
before intervention, 1 month after intervention, 3 months after intervention

Method of measurement
A 10-point VAS scale that the patient should give a score from 0 to 10

2

Description
The Disabilities of the Arm, Shoulder and Hand (DASH)

Timepoint
before intervention, 1 month after intervention, 3 months after intervention

Method of measurement
DASH Questionnaire with 21 questions

3

Description
world health organization quality of life questionnaire (WHOQOL-BREF)
Timepoint
before intervention, 1 month after intervention, 3 months after intervention
Method of measurement
world health organization quality of life (WHOQOL-BREF) with 30 items

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The treatment is in 5 sessions using a 35 cm square electrode with a current of 2 miliAmp. During this intervention, the anode electrode is placed on the primary motor cortex on the opposite side of the most painful side and the cathode is placed on the opposite super-orbital side, which of course has a protective sponge and the width of the sponges is 16 square centimeters on the skin. The patient is placed and electrode contact is made with the patient. In the tDCS group, the excitation rate reaches 2.5 miliAmp from zero in the first 10 seconds, and this excitation lasts for 20 minutes and then reaches zero in 10 seconds.
Category
Treatment - Devices

2

Description
Control group: In the control group, in the initial 10 seconds, the excitation rate reaches 2.5mA from zero, and this excitation continues for 30 seconds, and then reaches zero in 10 seconds. The duration of use of tDCS will be 20 minutes and the duration of use will be only 30 seconds.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital in Tehran
Full name of responsible person
Leyla Yarmohamadi
Street address
Imam Reza hospital, Etemad zade street, Fatemi street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mostafa Shahrezaee
Street address
Medical University for the Islamic Republic of Iran's Army, Etemadzadeh Avenue, West Fatemi St., Tehran, Iran
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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
Leyla Yarmohammadi
Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

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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