

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of transcranial direct current stimulation combined with exercise therapy on pain, function and central pain inhibition mechanisms in subjects with Patellofemoral Pain: A clinical trial

Protocol summary

Study aim

The effects of transcranial direct current stimulation combined with exercise therapy on pain, function and central pain inhibition mechanisms in subjects with Patellofemoral Pain

Design

Randomized control trial with 2 group of control and treatment design of 32 patients, Double-blind, with a parallel group.

Settings and conduct

Patients are randomly assigned to either intervention or treatment groups at Golestan Hospital in Ahvaz. In this study, patients and assessors were blinded.

Participants/Inclusion and exclusion criteria

People with patellofemoral pain with over three years of experience, ranging in age from 18 to 40 years, especially with back or around patella pain. The patient will be excluded if he has any previous surgery or joint injury and soft tissue of the knee.

Intervention groups

Patients in the intervention group received TDCS initially and in the control group received sham for 20 minutes.

Main outcome variables

pain, level of function, pressure pain threshold, condition pain modulation, kinesiophobia

General information

Reason for update

Acronym

TDCS

IRCT registration information

IRCT registration number: **IRCT20191221045836N1**

Registration date: **2020-01-27, 1398/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-27, 1398/11/07**

Update count: **0**

Registration date

2020-01-27, 1398/11/07

Registrant information

Name

Foruzan Orak

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3335 7387

Email address

orak.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-10, 1398/10/20

Expected recruitment end date

2021-02-08, 1399/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of transcranial direct current stimulation combined with exercise therapy on pain, function and central pain inhibition mechanisms in subjects with Patellofemoral Pain: A clinical trial

Public title

The effects of transcranial direct current stimulation combined with exercise therapy on clinical outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Anterior knee pain Provoked pain with two physical activity of functional tasks: stairs climbing, squat, running, biking, jumping, prolonged sitting Painfull quadriceps isometric contraction at 60 degree of squat Pain with medial or lateral patellar facet palpation Minimal pain intensity with visual analog scale 3 of 10 Pain report more than 3 years

Exclusion criteria:

History of knee surgery ligament knee instability Meniscus injury symptoms or intra joint dysfunction Knee tendinitis (patellat tendinitis, iliotibial band and jumper's knee tendinitis, Pes anserinus tendinitis) Patients with Osgood-Shlatter or Sinding-Larsen-Johanssen Patellar instability and positive apprehension sign Traumatic patellar dislocation Concurrent pain in hip, sacroiliac & lumbar walking with assistance Systematic disorders (cardiovascular or rheumatology) that affect on lower limbs Knee structural disorders including knee varus and valgus Psychiatry disorders that affect on electroencephalography such as depression, autism, Schizophrenia Seizure and epilepsy

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be carried out by a computer-generated random number list prepared by an independent statisticianr with no clinical involvement in the trial. The patients were randomly assigned to one of the following two groups: transcranial direct current stimulation combined with exercise therapy (Group A) or exercise therapy (Group B) The allocation was concealed in opaque, sealed envelope. A research assistant open the envelopes to reveal group allocation before starting the intervention

Blinding (investigator's opinion)

Double blinded

Blinding description

The physiotherapist that collected the data and patients were not aware of the group assignment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd., Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-01-06, 1398/10/16

Ethics committee reference number

IR.AJUMS.REC.1398.749

Health conditions studied

1

Description of health condition studied

Patellofemoral pain

ICD-10 code

M25.56

ICD-10 code description

Pain in knee

Primary outcomes

1

Description

pain

Timepoint

1 day before first session of treatment, second and twenty first days after end of treatment

Method of measurement

Visual Analog Scale

2

Description

Functional level

Timepoint

1 day before first session of treatment, second and twenty first days after end of treatment

Method of measurement

Lower limb functional scale questioner

3

Description

pressure pain threshold

Timepoint

1 day before first session of treatment, second and twenty first days after end of treatment

Method of measurement

Lutron tension and compression force gauge

4**Description**

Conditioned pain modulation

Timepoint

1 day before first session of treatment, second and twenty first days after end of treatment

Method of measurement

Conditioned pain modulation test score

5**Description**

Kinesiophobia

Timepoint

1 day before first session of treatment, second and twenty first days after end of treatment

Method of measurement

Tampa Scale for Kinesiophobia questioner

Secondary outcomes

empty

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

Intervention group: Combined exercise therapy and transcranial direct current stimulation Control group: Exercise therapy

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan Hospital

Full name of responsible person

Saadat Maryam

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Mofid Ave., Golestan Blvd., Ahvaz Town., Golestan Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Foruzan Orak

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The person's information will be confidential and the results will be as collective statistics

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

This clinical trial will be an research article and its protocol, results report and statistical analysis will be published to be used by therapists.

When the data will become available and for how long

If the journal has requested access to the data at any time, the data will be provided.

To whom data/document is available

Journal editors and Reviewers

Under which criteria data/document could be used

Sometimes for re-analysis or for use in meta-analysis studies

From where data/document is obtainable

Project Manager

What processes are involved for a request to access data/document

It should be send email to project manager and after reviewing the reason for requesting the data, they will be send

Comments