

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the Therapeutic Effect of Transcutaneous Electrical Nerve Stimulation (TENS) with Transcranial Direct Current Stimulation (TDCS) in Patients with Knee Osteoarthritis

Protocol summary

Study aim

Determining the therapeutic effect of TENS in comparison with TDCS in patients with knee osteoarthritis

Design

This is single blinded clinical trial, with parallel groups, with 40 patients suffering knee osteoarthritis, referring to the physical medicine and rehabilitation clinics of IRAN university of medical sciences in 1398. The patients are divided into 2 parallel groups by block randomization using sealed envelopes, and follow up are considered for 4 and 12 weeks later. The inclusion criteria are age over 50 years and VAS ≥ 4 . Follow up is performed immediately, 4 and 12 weeks later.

Settings and conduct

Our study is performed on the patients with knee osteoarthritis, referring to physical medicine and rehabilitation clinics of Iran university medical sciences during 1398. Blinding is applied on the analyzer (Person who analyze data, do not know about 2 different methods of stimulation). The patients are divided into 2 groups by block randomization using sealed envelopes.

Participants/Inclusion and exclusion criteria

Knee Osteoarthritis based on American College of Rheumatology criteria in Grades 1, 2 and 3 according to Lawrence - Kellergan criteria. People with idiopathic osteoarthritis and VAS ≥ 4 based on ACR criteria. Knee pain for at least six months. Over 50 years old.

Intervention groups

Group A or control group in which patients treated with TENS, 6 sessions, 3 times a week, with knee-strengthening exercises, and Group B or intervention group, in which patients treated with TDCS, 6 sessions, 3 times a week, with the mentioned exercises.

Main outcome variables

Pain intensity (VAS) and WOMAC score in both groups will be determined and then this criteria evaluated at

immediately, one month and three months post treatment. The results will be compared before and after injection in each group and between the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190804044431N1**

Registration date: **2019-10-18, 1398/07/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-18, 1398/07/26**

Update count: **0**

Registration date

2019-10-18, 1398/07/26

Registrant information

Name

Malihe karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1201

Email address

karimi_malihe@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Therapeutic Effect of Transcutaneous Electrical Nerve Stimulation (TENS) with Transcranial Direct Current Stimulation (TDCS) in Patients with Knee Osteoarthritis

Public title

Compare the effect of TDCS with TENS on osteoarthritis of the knee

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Knee Osteoarthritis based on American College of Rheumatology criteria in Grades 1, 2 and 3 according to Lowrence - Kellergan criteria People with idiopathic osteoarthritis and VAS ≥ 4 based on ACR criteria No Radicular Low Back Pain The absence of any neurological and musculoskeletal diseases that affect lower extremity function No diabetes No major depression disease No Drug abuse Knee pain for at least six months Over 50 years old No any acute or chronic infection No pregnancy or no pregnancy decision No inflammatory arthritis or secondary osteoarthritis No history of knee surgery No underlying disease of seizure No unstable conditions No metal objects near the electrode Patients not using Synchronous Pacemakers

Exclusion criteria:

The willingness of patients to exit from the study at any stage of the study

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization using sealed envelopes into 2 groups

Blinding (investigator's opinion)

Single blinded

Blinding description

Person who analyze data, do not know about the distribution of patients to the two treatment groups with Transcutaneous Electrical Nerve Stimulation and Transcranial Direct Current Stimulation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran Town

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-11-20, 1397/08/29

Ethics committee reference number

IR.IUMS.FMD.REC.1397.244

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

Knee Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

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

The severity of knee pain

Timepoint

The severity of knee pain before, immediately, 1 and 3 months after study initiation

Method of measurement

Visual Analogue Scale

2**Description**

The severity of symptoms and functional limitations

Timepoint

The severity of symptoms and functional limitations before, immediately, 1 and 3 months after study initiation

Method of measurement

By using WOMAC questionnaire

Secondary outcomes

karimi_malihe@yahoo.com

1

Description

Side effects

Timepoint

4 and 12 weeks later

Method of measurement

Physical Examination

Intervention groups

1

Description

Intervention group: In this group, patients receive 6 sessions of TDCS treatment (2 mA intensity for 20 minutes and two 35cm² electrodes that anode pole placed at the motor area and cathode pole positioned at the supraorbital area the opposite side of involved knee) 3 times a week combined with knee strengthening exercises (Close kinematic chain type twice a day) which are taught by a physical medicine and rehabilitation specialist

Category

Treatment - Devices

2

Description

Control group: In this group, patients receive 6 sessions of TENS treatment (100 Hz conventional TENS and 100 µs pulse width and the intensity of 10% below the patient's motor threshold, for 25 minutes) 3 times a week combined with knee strengthening exercises (Close kinematic chain type twice a day) which are taught by a physical medicine and rehabilitation specialist

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Firuzgar hospital

Full name of responsible person

Malihe karimi

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Department of Physical Medicine and Rehabilitation,
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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Malihe Karimi

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

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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