

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Clinical trial of effects of transcranial direct current stimulation (TDCS) on pain intensity and disability level of patients with chronic non specific low back pain

Protocol summary

Summary

The aim of this study is to determine the effect of transcranial direct current stimulation in patients with chronic mechanical low back pain in both intervention and control groups. 35 people will be in each group randomly. None of the participants will know which groups is belonging to (one way blindness). Inclusion criteria include a history of mechanical low back pain in the last 3 months, older than 18 years and less than 55 years. All these patients are initially musculoskeletal examination. Then for the control and patient groups Celecoxib (anti-inflammatory inhibitor of COX2) at a dose of 100 mg daily starts. Transcranial direct current stimulation is used for patients by ENRAF device made in Netherlands also sham group using the same device (disable mode), then the results will be discussed in two groups. In every session the assessment will be done by pain intensity questionnaire (VAS) and disability questionnaire (OSWESTRY) will be completed by the patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015113025314N1**

Registration date: **2016-05-05, 1395/02/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

Samane Sedighi

Name of organization / entity

Aja University of Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

501 Hospital of Aja University of Medical Sciences

Expected recruitment start date

2016-03-05, 1394/12/15

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of effects of transcranial direct current stimulation (TDCS) on pain intensity and disability level of patients with chronic non specific low back pain

Public title

Effect of transcranial direct current stimulation on lowback pain

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: low back pain history for 3 months; age 18-55. exclusion criteria: history of severe trauma to the low back; history of cancer; history of steroid use; severe weight loss; significant morning stiffness; signs of

infection such as fever; night sweats; peripheral joint involvement; positive family history of rheumatic diseases; non-mechanical nature of pain (night pain, unrelated to activity); progressive muscle weakness; neurological defects; incontinence of urine and feces; evidence of spinal cord injury; radiculopathy; immunodeficiency disease; history of spinal surgery in the past year; neurodegenerative diseases; mental illness; pregnancy; dizziness; headaches; ear pain increased continuously.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

blocking method is considered for randomization

Secondary Ids

empty

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

Ethics committee of Aja University of Medical Sciences

Street address

Etemadzade avenue, Fatemi street, Tehran

City

Tehran

Postal code**Approval date**

2015-09-28, 1394/07/06

Ethics committee reference number

IR.AJAUMS.REC.1394.28

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

MECHANICAL LOWBACK PAIN

ICD-10 code

M99.9

ICD-10 code description

Biomechanical lesion, unspecified

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

disability intensity

Timepoint

before intervention, imidiatly after intervention, 1 month after intervention, 3 month intervention

Method of measurement

OSWESTRY questionnaire

2**Description**

pain intensity

Timepoint

before intervention, imidiatly after intervention, 1 month after intervention, 3 month intervention

Method of measurement

VAS quastionaire

Secondary outcomes

empty

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

intervention group: using Celecoxib capsule 100 mg daily and using tDCS device for 5 days, 20 minutes

Category

Treatment - Other

2**Description**

control group: using Celecoxib capsule 100 mg daily and using sham status of tDCS device for 5 days, 20 minutes

Category

Treatment - Other

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

501 aja hospital

Full name of responsible person

Behrouz tavana

Street address

Etemadzade avenue, Fatemi street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Aja University of Medical Sciences

Full name of responsible person

Behrouz Tavana

Street address

Etemadzade avenue, Fatemi street, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Aja University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

AJA university of Medical Sciences

Full name of responsible person

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Position

physical medicine and rehabilitation

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty