Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 is 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 asesment 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

Iran (Islamic Republic of)

Phone

+98 21 8802 8931

Email address

s84sedighi@ajaums.ac.ir

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 quastionaire

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
Samane Seddighi
Position
physical medicine and rehabilitation
Other areas of specialty/work
Street address
Etemadzade avenue, Fatemi street,Tehran, ,
City
Tehran
Postal code
Phone
+98 21 4382 3476
Fax
Email
s84sedighi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Aja University of Medical Sciences
Full name of responsible person
Samane Seddighi
Position
specialist in physical medicine and rehabilitation
Other areas of specialty/work
Street address
Etemadzade avenue, Fatemi street,Tehran
City
Tehran
Postal code
Phone
+98 21 4382 3476
Fax
Email
s84sedighi@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Aja University of Medical Sciences
Full name of responsible person
Samane Seddighi
Position
Specialist in physical medicine and rehabilitation
Other areas of specialty/work
Street address
Etemadzade avenue, Fatemi street,Tehran
City
Tehran
Postal code
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+98 21 4382 3476
Fax
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s84sedighi@gmail.com
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