

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of stimulation on fear of pain in people with chronic low back pain with high fear

Protocol summary

Study aim

The effect of trans cranial direct current stimulation on fear of pain in patients with low back pain

Design

tDCS is applied for 5 days. The scores of fear of pain and disability from low back pain disorder investigated immediately after applying tDCS in the first session and after 5 days.

Settings and conduct

Persons volunteering to participate in the project are invited to the Neuro muscular Rehabilitation Center of semnan University of Medical Sciences. At the time of the entry, the form containing information of plan and Informed consent, the personal profile and fear of pain and disability questionnaire are completed

Participants/Inclusion and exclusion criteria

inclusion criteria: 1-People who have back pain for at least 2 months ago, 2-People who have pain intensity less than 3 3-People who have score more than 30 in the pain anxiety symptom scale (PASS) questionnaire. 4- People with low back pain who had no history of physiotherapy exclusion criteria: 1-People with vertebral fractures 2- People have lumbar spondilolisthesis vertebra higher than grade 2. 3-People who have defects in the sensory and motor nerves conduction of 4- People with headaches and neurological defects

Intervention groups

1) transcranial direct current stimulation on dorsolateral prefrontal area 2) transcranial direct current stimulation on SHAM

Main outcome variables

1-Fear of pain rate 2-Disability rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190311043012N2**

Registration date: **2019-06-27, 1398/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-27, 1398/04/06**

Update count: **0**

Registration date

2019-06-27, 1398/04/06

Registrant information

Name

pooran madani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3332 8502

Email address

pooran.madani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-10, 1398/02/20

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of stimulation on fear of pain in people with chronic low back pain with high fear

Public title

The effect of brain current stimulation on fear of pain in chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People who have back pain for at least 2 months ago, those who have pain intensity less than 3 People who have score more than 30 in the pain anxiety symptom scale (PASS) questionnaire. People with low back pain who had no history of physiotherapy

Exclusion criteria:

People with vertebral fractures have lumbar spondylolisthesis vertebra higher than grade 2 People who have defects in the speed of conduction of the sensory and motor nerves. People with headaches and neurological defects.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization of random numbers that arranged as non-ordinating numbers in a table and read in the lower order. The names of people with the specified code are arranged in the table and these numbers are read from top to bottom of the table. The first 25 people in the intervention group and rest of them located in the sham group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The tDCS will be used on the control group participants from the beginning of the treatment session, but the duration of the current is only 30 seconds, and after disconnection of the electrical current, the electrodes remain on the respective brain regions for 20 minutes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Semnan University of Medical

Science

Street address

Tabatabaee clinic, Mashahir squar, Ghods blvd

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2019-04-16, 1398/01/27

Ethics committee reference number

IR.SEMUMS.REC.1397.270

Health conditions studied

1

Description of health condition studied

low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

1-Fear of pain rate

Timepoint

At the beginning of the study, immediately and 5 days after the end of the intervention

Method of measurement

PASS (Pain Anxiety Symptom Scale) questionnaire

Secondary outcomes

1

Description

disability

Timepoint

before, immediately and 5 days after last session of intervention

Method of measurement

Roland Morris Disability questionnaire

Intervention groups

1

Description

Intervention group: trans cranial direct current stimulation with mA and 20 minutes on dorsolateral prefrontal in Consecutive 5 days

Category

Treatment - Devices

2

Description

Control group: Trans cranial direct current stimulation of the brain to trade off for 20 minutes (The current there was only in the first 30 seconds)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Dr. Rosita Hedayati

Street address

Faculty of Rehabilitation, Educational and therapeutic complex of Semnan university of medical sciences, 5 km of Damghan road

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Web page address

Sponsors / Funding sources

1

Sponsor

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President-office@semums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

pooran madani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Head of the Faculty of Rehabilitation and Scientific Research

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Semnan University of Medical Sciences

Full name of responsible person

Pooran madani

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Neuromuscular Rehabilitation Research

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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available