

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative effect of anodal and cathodal direct cerebral electrical stimulation on postural control in chronic low back pain patients with high pain-related anxiety

Protocol summary

Study aim

Comparative effect of anodal and cathodal direct cerebral electrical stimulation on postural control in chronic low back pain patients with high pain-related anxiety

Design

Clinical trial with parallel control group, double blind, randomized, Control with placebo, single center trial, Sample size 66 people.

Settings and conduct

Neuromuscular Rehabilitation Research Center, Semnan. Study participants and evaluators are unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-45 years old, right-handed, anxiety score due to pain more than 30, suffering chronic low back pain; pain score less than 3 out of 10 on a visual analog scale. Exclusion criteria: neurological and cerebellar diseases, psychological illnesses; structural deformities in the spine and lower extremities, abnormalities in the vestibular system.

Intervention groups

Intervention group 1: According to the treatment protocol, Anodal trans-cranial direct current stimulation (a-tDCS) is applied to the affected motor cortex is performed for patients. Intervention group 2: According to the treatment protocol, Cathodal trans-cranial direct current stimulation (c-tDCS) is applied to the affected motor cortex is performed for patients. Control group: Based on the treatment protocol, placebo stimulation is applied for patients.

Main outcome variables

-Postural stability in one static and two dynamic conditions in level 7 and 4. (with both feet under open and closed eyes conditions during a 30 seconds trial, before, immediately, 48 hours and one-week after tDCS intervention). -Error rate (number of errors/number of

auditory signals (during 30 seconds test-7 trial)) and reaction time during the auditory stroop task in dual take test.

General information

Reason for update

Defective information in the design variables section.

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N46**

Registration date: **2019-11-27, 1398/09/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-12, 1399/11/24**

Update count: **1**

Registration date

2019-11-27, 1398/09/06

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-16, 1398/03/26

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of anodal and cathodal direct cerebral electrical stimulation on postural control in chronic low back pain patients with high pain-related anxiety

Public title

Comparative effect of anodal and cathodal direct cerebral electrical stimulation on postural control in chronic low back pain patients with high pain-related anxiety

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

20-45 years old; Right-handed patients; Having pain-related anxiety score more than 30, based on Pain Anxiety Symptoms Scale (PASS) Suffering from chronic LBP (for more than six weeks or recurrent LBP with at least three episodes lasted more than one week over the past 12 months) A pain score less than 3 out of 10 on a visual analog scale (VAS) on the testing day

Exclusion criteria:

Any history of neurological diseases, such as Parkinson's Disease, Alzheimer Reporting any history of psychological illnesses Presence of any signs of radiculopathy or root lumbar spinal cord involvement Structural deformities in the spine or the lower extremities such as scoliosis, kyphosis, or lordosis Any abnormalities in the vestibular system Cerebellar disorders

AgeFrom **20 years** old to **45 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **66****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients are allocated randomly with simple sequential allocation in one of the two study groups by help of sealed envelope and receive the intervention of the same group. The unit of randomization is patient. Sealed envelopes are delivered to expert. With each patient's visit, one of the envelopes is randomly selected by the patients and determines the study group. The stratification approach is not used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study participants and evaluators are unaware of the allocation of study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee National Institute for Medical Research Development

Street address

No. 2, Besat Street, West Fatemi Street, Tehran

City

Tehran

Province

Tehran

Postal code

1419693111

Approval date

2019-06-16, 1398/03/26

Ethics committee reference number

IR.NIMAD.REC.1398.251

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

Chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

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

Static and dynamic balance evaluation (in static and 4,7 level of dynamic condition; with both feet under open and closed eyes conditions during a 30 seconds trial)

Timepoint

Before and immediately ,48 hours and one week after intervention

Method of measurement

Biodex Balance System (BBS) (302-950 model, Biodex Medical Systems, Inc. 20, New York, USA)

Secondary outcomes

1

Description

Error rate (number of errors/number of auditory signals(during 30 seconds test-7 trial)) during the auditory stroop task in dual take test

Timepoint

Before and immediately ,48 hours and one week after intervention

Method of measurement

Auditory stroop task (AST) written by a programmer and implemented by Matlab (R2018A, Mathworks, Navick, MA, USA) software

2

Description

Reaction time during the auditory stroop task in dual take test (the interval between the two consecutive stimuli will be randomized (2,000 ms to 3,000 ms). All reactions with response delays longer than 3,500 ms will be discarded)

Timepoint

Before and immediately ,48 hours and one week after intervention

Method of measurement

Auditory stroop task (AST) written by a programmer and implemented by Matlab (R2018A, Mathworks, Navick, MA, USA) software

Intervention groups

1

Description

Intervention group1: According to the treatment protocol, Anodal trans-cranial direct current stimulation (a-tDCS) is applied to the affected motor cortex is performed for patients.

Category

Rehabilitation

2

Description

Intervention group 2: According to the treatment protocol, Cathodal trans-cranial direct current stimulation (c-tDCS) is applied to the affected motor cortex is performed for patients.

Category

Rehabilitation

3

Description

Control group: Based on the treatment protocol, placebo stimulation is applied for patients.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Fatemeh Ehsani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

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

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

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mona Masoudi

Position

student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

Only available to scholars working in academic institutions.

Under which criteria data/document could be used

In case of relevant studies.

From where data/document is obtainable

Fatemeh Ehsani. Neuromuscular Rehabilitation Research Center, Ghods Blvd. +98 9191310755

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

-

Comments