Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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:20-45years old,right-handed,anxiety score due to pain more than30,suffering chronic low back pain; pain score less than3out of10on 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 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. Intervention group2: 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

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Alireza Emadi

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
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target 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
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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
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
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