Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of cerebral and peripheral electrical stimulation on brain activity in individuals with non-specific chronic low back pain

Protocol summary

Study aim

The aim of this study is to compare the effects of cerebral and peripheral electrical stimulation on brain activity, pain intensity, pain perception, pressure pain threshold, amount of lumbar flexion and functional performance of patients with non-specific chronic low back pain.

Design

This study is a randomized, triple blind clinical trial (patient, test and data analyzer) with three parallel intervention groups. 30 non-specific chronic low back pain patients will be randomly assigned into three treatment groups using covariate adaptive randomization method. Obviously, a code is assigned to each participant to hide the type of intervention.

Settings and conduct

This is a blinded triple study in which patients do not have any knowledge of the three groups of interventions they are supposed to compare, in addition to the test and analyst of the data, they are unaware of the grouping of patients. Patients with non-specific chronic low back pain (Ahvaz city) will be randomly assigned to three treatment groups at the specialized clinic of Ahvaz Jundishapur rehabilitation faculty. In the first group, the participants receive real peripheral and cerebral stimulation, the second group receives the real cerebral and sham peripheral stimulation and the third group receives real peripheral and sham cerebral stimulation. To stimulate the brain transcranial direct current stimulation device (tDCS), and transcutaneous electrical nerve stimulation device (TENS) will be used to stimulate the peripheral. For sham treatment, device will be placed on the treatment area, but after 30 seconds, the device will be turned off. In total, patients receive 10 sessions of therapy, at a frequency of five times a week, and each session will receive a 30-minute TENS and 20-minute tDCS and the effect of these electrical stimulation investigate immediately at the end of the first session and one day after the tenth session on absolute and relative power of brain activity, pain intensity, pain perception, pressure pain threshold, amount of lumbar flexion and functional ability .In the end, for survival, the treatment results are followed one month after the end of the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 30-50 years, Pain intensity greater than 30 based on 100 mm visual analogue Scale at least six month; Exclusion criteria: a history of non-cured systemic diseases including musculoskeletal, respiratory, cardiovascular, and hormonal diseases, and malignancies, â history of neurological disorders such as a headache, Seizure, polyneuropathy, a history of psychological disorders such as anxiety, depression and phobia, spondylolysis and spondylolisthesis, history of low back surgery, history of trauma in low back one year before this study, herniated disk with pressure effect on nerve root and pay attention to patient MRI report, current pregnancy, current use of effective medication on brain activity, alcoholism and addiction, use of transcranial direct current stimulation (tDCS) and transcutaneous electrical nerve stimulation (TENS) in 6 months a go

Intervention groups

30 patients with chronic non-specific low back pain will be randomly assigned into 3 treatment groups. The first group receives real transcutaneous electrical nerve stimulation and real transcranial direct current stimulation, the second group receives real transcranial direct current stimulation and sham transcutaneous electrical nerve stimulation and the third group receives real transcutaneous electrical nerve stimulation and sham transcranial direct current stimulation.

Main outcome variables

Absolute power index based on quantitative Electroencephalography; Relative power index based on quantitative Electroencephalography; Pain intensity based on visual analog scale; Pain perception based on McGill pain questionnaire; Pressure pain threshold based on the number of pressure algometer; Lumbar flexion based on Schober's test; Functional ability based on the

score of the oswestry disability questionnaire and Sit-to-Stand and Stand-to-Sit and up and go

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20140705018362N3**
Registration date: **2018-03-13, 1396/12/22**
Registration timing: **prospective**

Last update: **2018-03-13, 1396/12/22**
Update count: **0**
Registration date
2018-03-13, 1396/12/22

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-02, 1397/01/13
Expected recruitment end date
2018-07-20, 1397/04/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of cerebral and peripheral electrical stimulation on brain activity in individuals with non-specific chronic low back pain

Public title
Effect of cerebral and peripheral electrical stimulation on non-specific chronic low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 30-50 years A history of non-specific chronic Low Back Pain for at least six months OR a history of three episodes of Low Back Pain in the last year which were associated with activity limitation for more than 3 days or had required medical intervention Pain intensity greater than 30 based on 100 mm visual pain Scale
Exclusion criteria:
A history of non-cured systemic diseases including musculoskeletal, respiratory, cardiovascular, hormonal diseases, and malignancies A history of neurological disorders such as a headache, Seizure, polyneuropathy A history of psychological disorders such as anxiety, depression and phobia Addiction and alcoholism Taking medications that affect brain activity Brain implant Spondylolysis and Spondylolisthesis A history of low back surgery A history of trauma to lower back in the last year Herniated disk with clinical or/and imaging sign of nerve root involvement A history of treatment by transcranial direct current stimulation (tDCS) and/or transcutaneous electrical nerve stimulation (TENS) in the last six months Pregnancy
Age
From **30 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The balanced randomization using the covariate adaptive randomization technique described by Taves. First, We will assign a number of participants in each group using sequentially numbered, opaque, sealed envelopes. Then, the Taves method will be used to balance participants in the groups based on the important covariates such as sex and age.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The data analyst and the outcome assessor will be blinded to group allocation of each participant.Participants will not be aware of their group allocation (there is 3 experiment group)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Central Office, University Campus, Golestan
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2017-12-20, 1396/09/29
Ethics committee reference number
IR.AJUMS.REC.1396.713

Health conditions studied

1

Description of health condition studied
Chronic non-specific low back pain
ICD-10 code
M54.9
ICD-10 code description
Dorsalgia, unspecified

Primary outcomes

1

Description
Pain Intensity
Timepoint
One day before the treatment, one day, ten days and one month after the treatment
Method of measurement
Visual Analog Scale

2

Description
Oswestry Disability Index Score
Timepoint
One day before the treatment, one day, ten days and one month after the treatment
Method of measurement
Oswestry Disability Questionnaire

3

Description
The absolute power of the brain activity
Timepoint
One day before the treatment, one day, ten days and one month after the treatment
Method of measurement
Quantitative electroencephalography

4

Description
The relative power of the brain activity
Timepoint
One day before the treatment, one day, ten days and one month after the treatment
Method of measurement
Quantitative electroencephalography

5

Description
Functional Level
Timepoint
One day before the treatment, one day, ten days and one month after the treatment
Method of measurement
Sit-to-Stand and Up and Go tests

Secondary outcomes

1

Description
Lumbar flexion range of motion
Timepoint
One day before the treatment, and one day, ten days and one month after the treatment
Method of measurement
Schober Test

2

Description
Pressure Pain Threshold
Timepoint
One day before the treatment, and one day, ten days and one month after the treatment
Method of measurement
An algometry device

Intervention groups

1

Description
The intervention group 1: In this group, participants will receive 10 sessions of real cerebral and peripheral electrical stimulation, 5 days a week, for two weeks. The cerebral stimulation will be applied using a transcranial direct current stimulation (2 mA, energy density of 0.057 mA per square centimeter). The peripheral electrical stimulation will be applied using a Transcutaneous electrical nerve stimulation apparatus (100 Hz frequency, a pulse duration of 200 µs, asymmetrical biphasic square wave). TENS current intensity will be regulated according to the patient sensory threshold, characterized as an intense, yet comfortable. In each treatment session, patients will receive 20 min cerebral electrical stimulation, and 30 min peripheral electrical stimulation.
Category
Rehabilitation

2

Description
The intervention group 2: Participants will receive real cerebral and sham peripheral stimulation. For sham peripheral stimulation, TENS adjustment will be similar to the group 1. But in this group, 30 sec after adjustment of the intensity of stimulation, the TENS machine will be switched off.

Category
Rehabilitation

3

Description
The intervention group 3: Participants will receive sham cerebral and real peripheral stimulation. For sham cerebral stimulation, the cerebral stimulation set up will be similar to the other groups. But after 30 sec the tDCS machine will be switched off.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Rehabilitation Clinics of School of Rehabilitation Sciences, Ahvaz Jundishapur University of Medica

Full name of responsible person
Fateme Esfandiarpour

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Sponsors / Funding sources

1

Sponsor

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Web page address

Grant name
IR,AJUMS, REC

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Fateme Esfandiarpour

Position
Assistant professor

Latest degree
Ph.D.

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Biomechanics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
one year after publication, all of participants data (without identifiers) collected during the trial will be shared The study's protocol will be submitted for publication in an international journal, following registration of the trial in IRCT. The study's protocol will contain statistical analysis plan. We plan to inform Health Care Professionals of our findings by submitting our results for publication in international scientific journals. Furthermore, the results of our research will be shared with researchers at national and international scientific meetings and conferences.
When the data will become available and for how long
One year after publication
To whom data/document is available
Researchers and health professionals
Under which criteria data/document could be used
Research and clinical use.
From where data/document is obtainable
Secure scientific websites and the researchers of the study Scientific website Journals, and search engines such Google Scholars, Research gate, and Pubmed
What processes are involved for a request to access data/document
Online access via scientific websites or email to the investigators
Comments