

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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, a 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 ago

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

Name

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Name of organization / entity

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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

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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 μ s, 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 Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

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Full name of responsible person

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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.

Other areas of specialty/work

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**Person responsible for updating data****Contact****Name of organization / entity**

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