

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The Effect of Transcranial Electrical Stimulation of the Primary Motor and Sensory Cortex on the Feed-forward and Feedback Strategies in Response to Predictable External Perturbations in Patients with Chronic Low Back Pain

Protocol summary

Study aim

The Effect of Transcranial Electrical Stimulation of the Primary Sensory and Motor Cortex on Feed-forward and Feedback Strategies in Response to Predictable External Disturbance in Patients with Chronic Low Back Pain

Design

A Clinical Trial with Two Control Groups, with Parallel Groups, Double-blind, Randomization Sequence was through Randomization.com and Balanced Block Randomization Method

Settings and conduct

Rehabilitation Tehran University of Medical Sciences, Evaluations and Treatments were Performed in the Control Group (Sensory-Motor Training Group with Anodic tDCS Sham Flow) and in the Intervention Group (Sensory-Motor Training with Real tDCS Anodal Flow) for 4 Weeks and Re-evaluated 48 Hours after the Last Treatment Session. Patients are not Aware of their Treatment Group and the Analyzer is not Aware of the Patient Information Group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 20 - 50 years old Both genders LBP for more than 6(m) or LBP in 3 courses for more than 1(w) in past 12(w) Unilateral radicular pain secondary to disc herniation L4/L5 and L5/S1 diagnosed with MRI Positive of slump test or straight leg raise test or Lasegues's test. Pain from anterior lateral part of leg to back area of the leg associated with L4/L5 dermatome Average pain score ≥ 4 Oswestry disability index > 4 Exclusion Criteria: Participant dissatisfaction with the continuation of the program Absence for more than 2 sessions or for 3 times during the procedure The patient is under a therapeutic program

Intervention groups

Intervention group: Exercise therapy and real tDCS
Control group: Exercise therapy and placebo tDCS

Main outcome variables

Mean Integral Normalized Electromyographic Activity And Mean Latency of Electromyographic Activity of the Transverse Muscles of the Abdomen, Multifidus, and Gluteus Medius Ipsilateral and Opposite to Perturbations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220228054149N1**

Registration date: **2022-04-04, 1401/01/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-04, 1401/01/15**

Update count: **0**

Registration date

2022-04-04, 1401/01/15

Registrant information

Name

Hanie Sadat Hejazi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Transcranial Electrical Stimulation of the Primary Motor and Sensory Cortex on the Feed-forward and Feedback Strategies in Response to Predictable External Perturbations in Patients with Chronic Low Back Pain

Public title

Investigating the Effect of Brain Stimulation on Balance

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Suffering from LBP for more than 6 (m) or Experience LBP in 3 courses for more than 1 (w) in past 12 (w)
Unilateral Radicular Pain Secondary to Disc Herniation L4/L5 and L5/S1 Diagnosed with MRI Being Positive of Slump Test or Straight Leg Raise Test or Lasegues's Test
Pain from Anterior Lateral Part of Leg to Back Area of the Leg Associated with L4/L5 Dermatome to the Posterior Part of the Leg and Heel and Lateral Part of the Foot
Absence of any History of Brain Tumor, Brain Injury or Brain Stroke
Absence of any History of Spondylolysis, Spondylolisthesis and Spinal Cord Fractures
Absence of any History of Neurological Disease such as Parkinson, Cerebellum Disorders or Alzheimer
Absence of any History of Scratches or Cut on the Scalp
Average Pain Score ≥ 4 Oswestry Disability Index > 4 Mini Mental Status Examination ≥ 24 No Pregnancy
Absence of the History of Seizure No Implantation or Pulse Maker
Absence of the History of Dermal Infection
Age Range: 20 year - 50 year

Exclusion criteria:

Participant Dissatisfaction with the Continuation of the Program Being Absent for more than 2 Sessions or for 3 Times during the whole Procedure If the Patient is under a Special Therapeutic Program

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are Randomly Divided into Two Groups,

Which Will be Done Using Randomization Sequence through Randomization.com and Balanced Block Randomization Method. The Size of the Blocks is 4. Also, for Allocation Concealment, Sealed and Numbered Envelopes are Used, Which are Provided to the Participants by the Secretary.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are Randomly Divided into Two Groups of Real Treatment and Unreal(Placebo) Treatment Who do not Know the Type of their Group. The Information Obtained from the Evaluation of Patients is Categorized by another Person and the Analyst is not Aware of the Grouping of Information.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of School of Nursing, Midwifery and Rehabilitation Tehran University of Medical Sci

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Unit 6, No. 20, First Soleinami Ally, West Safa Ave., Imam Hossein Sq., Tehran Town

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Postal code

1153755171

Approval date

2022-02-23, 1400/12/04

Ethics committee reference number

IR.TUMS.FNM.REC.1400.210

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

Chronic Low Back Pain due to Radiculopathy

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Mean normalized iEMG of the ipsilateral transversus abdominis, multifidus, and gluteus medius in the four time windows (APA1, APA2, CPA1, and CPA2)

Timepoint

APA1 : -250 to -100 milliseconds, APA2 : -100 to +50 milliseconds, CPA1 : +50 to +200 milliseconds, CPA2 : +200 to +350 milliseconds

Method of measurement

Electromyography

2

Description

Mean normalized iEMG of the contralateral transversus abdominis, multifidus, and gluteus medius in four time windows (APA1, APA2, CPA1, and CPA2)

Timepoint

APA1 : -250 to -100 milliseconds, APA2 : -100 to +50 milliseconds, CPA1 : +50 to +200 milliseconds, CPA2 : +200 to +350 milliseconds

Method of measurement

Electromyography

3

Description

Mean onset latency of the ipsilateral transversus abdominis, multifidus, and gluteus medius

Timepoint

The time interval between perturbations (time 0) and the time of onset of muscle activity

Method of measurement

Electromyography

4

Description

Mean onset latency of the contralateral transversus abdominis, multifidus and gluteus medius

Timepoint

The time interval between perturbations (time 0) and the time of onset of muscle activity

Method of measurement

Electromyography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sensory-motor training in three stages of static, dynamic, functional and real tDCS in time for 4 weeks and 3 times a week (12 sessions), tDCS model neurostim2 model of Medina Teb Gostar company, electrode size 2*4cm, An active electrode (anode) on the M1 region, which according to the international system is

10-20 according to C3 or C4, An active electrode (anode) on the S1 region, which is 2 cm behind the C3 or C4, Reference electrodes (cathode) on the forehead and directly above the eyebrows, Device with an intensity of 1.5 mA and for 20 minutes, The beginning of the current, a period of 10 seconds ramping up, The end of the current, a period of 10 seconds ramping down

Category

Rehabilitation

2

Description

Control group: Sensory-motor exercises in three stages of static, dynamic and functional and tDCS as sham for 4 weeks and 3 times a week (12 sessions), tDCS for 20 minutes: placement of electrodes as intervention group, Device turned on and The intensity increases to the point that the patient feels a tingling sensation, but this feeling will be only for 10 seconds.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr.Mohammad Talebpour

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

Dr.Seyed Ahmadrza Khatonabadi

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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?

No

Title of funding source

Tehran University of Medical Science

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
Tehran University of Medical Sciences
Full name of responsible person
Dr.Roya Khanmohammdi
Position
Professor Assistant
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Person responsible for scientific inquiries

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Person responsible for updating data

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available