Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Country
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
Street address
Unit 6, No. 20, First Soleinami Ally, West Safa Ave., Imam Hossein Sq., Tehran Town
City
Tehran
Province
Tehran
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, APA1, 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
Street address
Sina hospital, Imam Khomeini St, Hassanabad Sq
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1136746911
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2

Recruitment center
Name of recruitment center
Tehran University of Medical Sciences - School of Rehabilitation
Full name of responsible person
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School of Rehabilitation, Corner of Safi Alishah St, Pich e Shemiran, Engheleb Eslami Ave
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Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Akbar Fotoohi
Street address
Deputy of Research and Technology, 6th floor, Central University Organization, Corner of Qods St, Keshavarz Blvd, Enghelab eslami Sq
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6511111489
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Email
vcr@tums.ac.ir
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
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
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Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
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hs-hejazi@student.tums.ac.ir

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