

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation Effectiveness of electro muscle stimulation and electro acupuncture in Reducing Pain and Improving the Performance of Patients with lumbar disk problem

Protocol summary

Study aim

Evaluation of efficacy of electro acupuncture and electro muscle stimulation in patients with chronic lumbar disc herniation

Design

Parallel Randomized Control Trial

Settings and conduct

Patients divided to three group .The place of work is sports medicine clinic of Imam Hossein hospital in Tehran. The first group is given that exercise with electroacupuncture.The SDZ-2 is operated for 15 minutes using an electro-puncture needle.three sessions per week for 12 sessions.the second group will do electrical muscle stimulation with veinoplus plus that exercise.The pads attach vertically to the paraspinal muscles in the L4-L5-S1 vertebrae.The third group is given exercise only. Pain score and Quebec questionnaire were completed by the patient at the beginning, at the end of the 12 sessions and after three months of the last session

Participants/Inclusion and exclusion criteria

A history of low back pain associated with degenerative intervertebral disc disease (bulging, mild protrusion) with neurologic diagnosis after examination and with pain lasting at least three months

Intervention groups

All three groups receive acetaminophen for their pain at a dose of 500 mg every 8 hours in case of severe pain. In addition, all patients will receive 8 exercises to strengthen core muscles and improve flexibility.exercise included: Pelvic bridge , Side bridge , curl-up , quadruped positions , alternate arm/leg raises , Prone plank , cate and camel , priformis stretch the first group:exercise with electroacupuncture the second group:exersice with electrical muscle stimulation the third group:just exercise

Main outcome variables

age;gender;smoking;alcohol;duration;comorbid

disease;Severity of pain ; Severity of disability; BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190826044615N1**

Registration date: **2019-11-09, 1398/08/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-09, 1398/08/18**

Update count: **0**

Registration date

2019-11-09, 1398/08/18

Registrant information

Name

Zeinab Faraji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8807 5911

Email address

zfaraji95@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Effectiveness of electro muscle stimulation and electro acupuncture in Reducing Pain and Improving the Performance of Patients with lumbar disk problem

Public title

Evaluation Effectiveness of electro muscle stimulation and electro acupuncture in Reducing Pain and Improving the Performance of Patients with lumbar disk problem

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

all patients with radicular low back pain that begins 3 months ago patients older than 18 years

Exclusion criteria:

all patients with non radicular low back pain patients under 18 years old

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is used to balance the number of samples. There are 6 different modes for triple blocks. Accordingly, patients are divided into 3 groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

2th floor no.8 6th tohid darya blv. shahrak garb

City

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Province

Tehran

Postal code

1466976413

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.SBMU.MSP.REC.1397.537

Health conditions studied

1

Description of health condition studied

chronic low back pain

ICD-10 code

M51.16

ICD-10 code description

Intervertebral disc disorders with radiculopathy, lumbar region

Primary outcomes

1

Description

low back pain

Timepoint

Baseline-- End of treatment session-Three months after the end of the intervention

Method of measurement

The Quebec Back Pain Disability Scale- Visual Analogue Scale) VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group(1):Performed using SDZ-2 and electro-puncture needles for a 15 minute period. Each session will take 15 minutes and three sessions per week for 12 sessions. 10 Probes Attach to Five Lead Bytes of Polarity Frequencies of stimulation will be close to pain tolerance-Intervention The first group in addition to the intervention received the exercises described in the previous sections.

Category

Rehabilitation

2

Description

Intervention group: group(2):This will be done using the veinoplus device. The pads are attached vertically to the paraspinal muscles in the L4-L5-S1 vertebrae.In addition, they receive exercise intervention

Category

Rehabilitation

3**Description**

Control group: receive exercise only

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam hosein hospital

Full name of responsible person

zeinab faraji

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2nd.floor no.8 6th tohid. darya blv. shahrak gharb

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

ali ziaee

Street address

2nd floor no.8 6th tohid darya blv shahrak gharb

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zeinab Faraji

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Position

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Phone**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

Not applicable

Data Dictionary

Not applicable