Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 electroacupucture the second group:exersice with electrical muscle stimulation the third group:just exersice

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

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Iran (Islamic Republic of)

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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 gharb
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tehran
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
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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 updating data

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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
Not applicable

Data Dictionary
Not applicable