Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effects of electroacupuncture versus acupuncture in radicular low back pain:A randomized controlled trial

Protocol summary

Study aim

To compare the effects of electroacupuncture and acupuncture, each combined with exercise therapy, on pain intensity and functional status in patients with MRI-confirmed radicular low back pain.

Design

A randomized, double-blind, parallel-group controlled clinical trial with 60 patients. Participants will be assigned to groups using block randomization.

Settings and conduct

This study will be conducted as a double-blind randomized clinical trial. The target population will include patients with radicular low back pain who attend the Sports Medicine Clinic at Rasoul Akram Hospital, affiliated with Iran University of Medical Sciences, in 2026 and 2027.

Participants/Inclusion and exclusion criteria

Inclusion criteria. Patients aged 18–65 years who provide lumbar magnetic resonance imaging (MRI) confirming lumbar disc herniation and have radicular symptoms.Exclusion criteria. A history of trauma, evidence of disc sequestration on lumbar MRI, an indication for disc surgery, strenuous occupational or nonoccupational physical activity during the study period, physiotherapy or therapeutic injections in the lumbar region (including steroid injections) within the previous three months, or a history of red-flag symptoms.

Intervention groups

Group 1 will receive acupuncture, and Group 2 will receive electroacupuncture. Both groups will receive treatment at lumbar and gluteal points three times a week for four weeks (12 sessions). Both groups will follow the same exercise therapy program and record their exercises in a logbook. Nonsteroidal anti-inflammatory drugs (NSAIDs) will be prohibited during the study, and acetaminophen will be permitted for severe pain.

Main outcome variables

Pain intensity; Disability level; Range of motion (ROM); Functional capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211116053072N4**
Registration date: **2026-11-14, 1405/08/23**
Registration timing: **prospective**

Last update: **2026-11-14, 1405/08/23**
Update count: **0**

Registration date

2026-11-14, 1405/08/23

Registrant information

Name

Hooman Angoorani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-12-21, 1405/09/30

Expected recruitment end date

2027-09-20, 1406/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effects of electroacupuncture versus acupuncture in radicular low back pain:A randomized controlled trial

Public title
Comparing the effects of electroacupuncture versus acupuncture in radicular low back pain:A randomized controlled trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 65 years Availability of a lumbar spine MRI confirming lumbar discopathy Definitive diagnosis of lumbar disc herniation confirmed by MRI, with associated radicular symptoms Radiating low back pain into the lower extremities persisting for at least one month, with a minimum pain intensity of 4 on the Visual Analogue Scale (VAS)." Body mass index (BMI) between 20 and 35 kg/m². Ability to undergo the planned therapeutic interventions (absence of a cardiac pacemaker and no functional limitations attributable to underlying medical conditions)

Exclusion criteria:
History of trauma or physical injury to the lumbar region Evidence of disc sequestration on lumbar spine MRI Presence of an indication for surgical disc repair based on clinical evaluation or imaging findings Engagement in strenuous physical activity (occupational or non-occupational) during the study period History of physiotherapy or any injection-based treatment (including corticosteroid injections) within the past three months History of low back pain attributable to inflammatory, infectious, or neoplastic causes Presence of red flags, including nocturnal awakening due to pain, night sweats, excessive weight loss within the past six months, or fever Pregnancy or a history of spinal surgery History of spinal disorders, including cauda equina syndrome, spondylolisthesis, or unstable spondylolysis History of psychiatric disorders or current use of psychotropic medication

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
An independent statistician who is not involved in participant recruitment, intervention delivery, or outcome assessment will generate the allocation sequence using a computerized random number generator and permuted blocks of fixed size six. Each block will contain three assignments to the acupuncture group and three to the electroacupuncture group in random order, yielding a 1:1 allocation ratio. The statistician will retain the allocation list, and the person responsible for recruitment will have no access to it. After eligibility is confirmed, informed consent is obtained, and the participant is enrolled, the statistician will use the next assignment in the sequence and communicate that participant’s group directly to the treating clinician.

Blinding (investigator's opinion)
Double blinded

Blinding description
The following individuals will be blinded to treatment allocation in this study: Pre- and post-intervention assessments and patient exercise therapy will be conducted by a sports medicine resident who is a member of the research team and will remain blinded to patients’ treatment allocation. Patients will be blinded to their assigned treatment group. Data analysis will be performed by a statistical consultant who will remain blinded to patients’ treatment allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Vice Presidency for Research and Technology, Central Headquarters Building, Iran University of Medical Sciences, Hemmat Expressway, near Milad Tower, Tehran, Iran.

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Tehran

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1455813643

Approval date
2026-05-21, 1405/02/31

Ethics committee reference number
IR.IUMS.FMD.REC.1405.152

Health conditions studied

1

Description of health condition studied
Radicular low backpain
ICD-10 code
M54.16
ICD-10 code description
Radiculopathy, lumbar region

Primary outcomes

1

Description
Pain intensity
Timepoint
Pain intensity will be assessed at baseline (prior to intervention), at the end of the fourth week (post-intervention), and at a three-month follow-up after the completion of either acupunctural or electroacupuncture therapy and therapeutic exercise.
Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Degree of disability
Timepoint
Disability severity will be assessed at baseline (prior to intervention), at the end of the fourth week (post-intervention), and at a three-month follow-up after the completion of either acupunctural or electroacupuncture therapy and therapeutic exercise.
Method of measurement
Oswestry Disability Index

2

Description
Functional capacity
Timepoint
functional capacity will be assessed at baseline (prior to intervention), at the end of the fourth week (post-intervention), and at a three-month follow-up after the completion of either acupunctural or electroacupuncture therapy and therapeutic exercise.
Method of measurement
6 Minutes Walk Test

3

Description
Lumbar flexion range of motion
Timepoint
Lumbar flexion range of motion (ROM) will be assessed at baseline (prior to intervention), at the end of the fourth week (post-intervention), and at a three-month follow-up after the completion of either acupunctural or electroacupuncture therapy and therapeutic exercise.
Method of measurement
Modified Schober Test

Intervention groups

1

Description
Intervention group: In this group, traditional Chinese acupuncture was administered by a licensed specialist using sterile, single-use needles. The selected acupoints included lumbar and gluteal points corresponding to the primary meridians (e.g., BL60, BL23, BL25, BL40, GB30, and GV3). Each session lasted 20 minutes, with treatment sessions conducted three times per week for four consecutive weeks (totaling 12 sessions). Additionally, patients were instructed to perform specific core and lumbar strengthening exercises according to a prescribed protocol and were required to record their compliance in a logbook.The prescribed exercises included:- Cat-Camel stretch- Supermans- Hamstring stretch- Bridge- Abdominal hollowing- Piriformis stretch
Category
Treatment - Devices

2

Description
Intervention group: Group 2: Electroacupuncture and Therapeutic ExerciseIn this group, the same acupoints selected in Group 1 are utilized; however, an electrical current with a mean frequency of 19 Hz and adjustable amplitude is applied via the needles. The stimulation intensity is titrated to the patient's maximum tolerable threshold. Similar to Group 1, sessions are conducted three times per week for four consecutive weeks (totaling 12 sessions). The exercise regimen is identical to that of Group 1, and compliance is recorded in a logbook.In both groups, patients are instructed to refrain from using non-steroidal anti-inflammatory drugs (NSAIDs), with the exception of acetaminophen, for the management of severe pain throughout the study period.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Iran 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

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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