Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative Study of Corticosteroid Injection in the Caudal Epidural Space Under Fluoroscopy Guidance With or Without Ozone Injection in Lumbo-Sacral Radiculopathy: A Single-Blind Clinical Trial

Protocol summary

Study aim

To compare the efficacy of fluoroscopic-guided caudal epidural steroid injections with and without ozone therapy in reducing pain and improving functional outcomes in patients with lumbosacral radiculopathy caused by lumbar disc protrusion

Design

A single-center, single-blind, parallel-group randomised controlled trial with 40 patients randomly assigned into two equal groups. The study will compare the efficacy of caudal epidural steroid injections with and without ozone therapy. Outcome assessment will be blinded to ensure unbiased results

Settings and conduct

A single-center, single-blind trial at Imam Khomeini Hospital, Tehran, Iran, using fluoroscopic guidance. Participants will be monitored for safety, with treatment allocation blinded to participants and outcome assessors

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 18–70 years with lumbosacral radiculopathy due to disc protrusion (L4-L5 or L5-S1) and symptoms persisting >3 months. Exclusion Criteria: History of spinal surgeries, severe systemic diseases, uncontrolled diabetes, infections, pregnancy, or cauda equina syndrome

Intervention groups

Group A: Caudal epidural steroid injection (8 mg dexamethasone, 5 mL lidocaine 1%, 3 mL normal saline). Group B: Same steroid injection as Group A + 5 mL ozone gas (10 µg/cc). Procedure: All injections under fluoroscopic guidance to ensure accuracy. The study compares the efficacy of steroid injections with and without ozone therapy for lumbosacral radiculopathy

Main outcome variables

Pain Intensity: Measured using the Visual Analog Scale (VAS), ranging from 0 (no pain) to 10 (worst pain). Functional Disability: Assessed with the Oswestry Disability Index (ODI), scored as a percentage (higher scores = greater disability). Timing of Measurements: At baseline, one month, and six months post-treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241214064051N1**
Registration date: **2025-02-15, 1403/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-15, 1403/11/27**
Update count: **0**

Registration date

2025-02-15, 1403/11/27

Registrant information

Name

Nima Amiresmaili

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

2025-01-24, 1403/11/05

Expected recruitment end date

2025-02-23, 1403/12/05

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Study of Corticosteroid Injection in the Caudal Epidural Space Under Fluoroscopy Guidance With or Without Ozone Injection in Lumbo-Sacral Radiculopathy: A Single-Blind Clinical Trial

Public title
Comparative Study of Corticosteroid Injection in the Caudal Epidural Space Under Fluoroscopy Guidance With or Without Ozone Injection in Lumbo-Sacral Radiculopathy: A Single-Blind Clinical Trial
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 70 years Diagnosed with low back pain (LBP) with radicular symptoms lasting more than three months and unresponsive to medical therapy, rest, and physical therapy Magnetic resonance imaging (MRI) evidence of lumbar intervertebral disc protrusion at the L4-L5 or L5-S1 levels
Exclusion criteria:
History of spinal fractures, inflammatory diseases, malignancy, or facet joint syndrome. Previous spinal surgeries uncontrolled diabetes mellitus neuropathy spondylolisthesis extruded discs severe knee osteoarthritis (grade 4), scoliosis clinical or laboratory evidence of infection Coagulopathy symptoms of cauda equina syndrome symptoms of cauda equina syndrome neurological disorders severe systemic diseases, mental illnesses current anticoagulant therapy Pregnancy or breastfeeding
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Forty patients meeting the inclusion criteria will be randomly assigned into two groups of 20 patients each using a computer-generated randomization list. Group A will receive a caudal epidural steroid injection, while Group B will receive the same injection plus ozone therapy. The participants and the physician assessing outcomes will be blinded to the type of procedure, though the operator performing the injections will be aware of the treatment administered.
Blinding (investigator's opinion)
Single blinded
Blinding description
In our randomized controlled trial comparing fluoroscopic-guided caudal epidural steroid injections with or without ozone therapy, we implemented blinding in specific groups to minimize bias. Below is a detailed description of the blinding process and its application to various roles involved in the study. 1. Participants (Patients) – Blinded The patients were unaware of which treatment they received (steroid injection alone or steroid + ozone injection). Since the injections were performed under the same procedural conditions for both groups, no distinguishing factors indicated the treatment assignment. 2. Principal Investigator – Not Blinded The principal investigator was involved in study design and oversight but was not blinded to treatment allocation. Given the need for procedural oversight and protocol adherence, they had access to treatment assignment information. 3. Healthcare Providers (Care Providers/Interventionists) – Not Blinded The physician performing the injections was aware of the treatment allocation since they had to prepare and administer the correct mixture. Due to the nature of the intervention (i.e., the inclusion of ozone gas in one group), it was not possible to blind the care provider. 4. Data Collectors – Blinded All data collectors, including those responsible for recording patient-reported pain scores and functional disability assessments, were blinded to the treatment assignment. This ensured that subjective measures such as the Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI) were not influenced by knowledge of group allocation. 5. Outcome Assessors – Blinded The physician assessing clinical outcomes (pain and disability scores) was blinded to the treatment groups. Outcome assessments were conducted at baseline, 1 month, and 6 months post-procedure without knowledge of whether the patient received steroids alone or steroids plus ozone. 6. Data Analysts – Blinded (Unclear, Needs Clarification) The data analyst responsible for statistical analyses may or may not have been blinded. If blinding was applied, the dataset would have been coded in a way that concealed treatment allocation. If unblinded, this may have introduced potential bias in the interpretation of results. 7. Data Safety and Monitoring Board (DSMB) – Not Applicable The study did not include an independent Data Safety and Monitoring Board (DSMB), as it was a relatively small-scale clinical trial without external oversight. 8. Manuscript Writers – Not Blinded The authors of the manuscript had access to full study data and treatment allocation, which allowed for an informed discussion of results and clinical implications. Summary of Blinding Implementation Group Blinding Status Rationale Participants (Patients) Blinded Ensured unbiased patient-reported outcomes (VAS, ODI). Principal Investigator Not Blinded Required for study design and oversight. Care Providers (Interventionists) Not Blinded Needed to prepare and administer treatment. Data Collectors Blinded Ensured unbiased data collection of patient responses. Outcome Assessors Blinded Prevented bias in evaluating clinical outcomes. Data Analysts Unclear Should ideally be blinded to prevent bias in analysis. DSMB Not

Applicable No external monitoring board was used. Manuscript Writers Not Blinded Required access to complete data for reporting. How Blinding Was Achieved Randomization: Patients were randomly assigned to two treatment groups using a computer-generated randomization list. Standardized Procedures: Both groups underwent identical procedural steps, making it difficult for patients to distinguish between treatments. Separate Roles: The care provider (interventionist) was separate from the outcome assessor, ensuring the assessment process remained unbiased. Blinded Data Collection: The individuals collecting VAS and ODI scores were unaware of treatment allocation. Potential Data Analysis Blinding: If implemented, treatment codes were masked until the final statistical analysis was completed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Human Research at Imam Khomeini Hospital.

Street address

Imam Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran

City

tehran

Province

Tehran

Postal code

1419733141

Approval date

2024-10-28, 1403/08/07

Ethics committee reference number

IR.TUMS.IKHC.REC.1403.315

Health conditions studied

1

Description of health condition studied

Lumbosacral Radiculopathy due to Lumbar Intervertebral Disc Protrusion (L4-L5 or L5-S1).This study focuses on chronic low back pain (LBP) with radicular symptoms, aiming to improve pain management and functional outcomes for patients with this condition.

ICD-10 code

M51.1

ICD-10 code description

Thoracic, thoracolumbar and lumbosacral intervertebral disc disorders with radiculopathy

Primary outcomes

1

Description

Pain IntensityMeasurement Method: Visual Analog Scale (VAS)Scale Range: 0 (No Pain) to 10 (Worst Pain Imaginable)Objective: To assess the patient's pain intensity before and after the intervention to determine treatment efficacy.Measurement Time Points: Baseline, 1 month, and 6 months post-injection

Timepoint

Pain IntensityMeasurement Method: Visual Analog Scale (VAS)Scale Range: 0 (No Pain) to 10 (Worst Pain Imaginable)Objective: To assess the patient's pain intensity before and after the intervention to determine treatment efficacy.Measurement Time Points:Before intervention (Baseline)1 month post-injection3 months post-injection6 months post-injection The measurement time points are clearly specified. The measurement method and scale range are explicitly stated

Method of measurement

Pain IntensityMeasurement Method: Visual Analogue Scale for PainMeasurement Tool: Visual Analogue Scale Ruler for PainScale Range: 0 (No Pain) to 10 (Worst Pain Imaginable)Objective: To assess the patient's pain intensity before and after the intervention to determine treatment efficacy.Measurement Time Points:Before the intervention (Baseline)One month after injectionThree months after injectionSix months after injection

2

Description

Functional Disability

Timepoint

Before the intervention (Baseline)One month after injectionThree months after injectionSix months after injection

Method of measurement

Measurement Method: Oswestry Disability IndexMeasurement Tool: Oswestry Disability Index QuestionnaireUnit of Measurement: Percentage of functional disability caused by low back painObjective: To assess the effect of treatment on patients' functional ability and reduction of limitations caused by pain Measurement

Secondary outcomes

1

Description

Quality of Life

Timepoint

Time Points:Before the intervention (Baseline)One month after injectionThree months after injectionb Six months after injection

Method of measurement

Measurement Method: World Health Organization Quality of Life Questionnaire Measurement Tool: World Health Organization Quality of Life Questionnaire – Short Version

(26 Questions)Unit of Measurement: Quality of life score based on participants' responses

Intervention groups

1

Description
Intervention Group:Group B (Steroid + Ozone Group):This group will receive the same steroid injection as the control group, with the addition of ozone gas.Injection Details:Steroid Composition:8 mg dexamethasone.5 mL of 1% lidocaine.3 mL of normal saline.Additional Component:5 mL of ozone gas at a concentration of 10 µg/cc.Procedure:All injections will be performed under fluoroscopic guidance in a sterile environment to ensure precise catheter placement in the epidural space.

Category
Treatment - Other

2

Description
Control group:Group A (Steroid Group):This group will serve as the control group in the study and will receive only the steroid injection.Injection Details:Steroid Composition:8 mg dexamethasone.5 mL of 1% lidocaine.3 mL of normal saline.Procedure:All injections will be performed under fluoroscopic guidance in a sterile environment to ensure precise catheter placement in the epidural space.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Tehran, Iran.

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
Tehran 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

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Non-Faculty Specialist Physician

Latest degree
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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