Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative effectiveness of triamcinolone alone versus triamcinolone and hyaluronidase or triamcinolone with erythropoietin in epidural injections for lumbosacral radiculopathy: A randomized controlled trial

Protocol summary

Study aim
Comparing the effect of epidural injection of triamcinolone, combination of triamcinolone and hyaluronidase or erythropoeitin on clinical symptioms of patients with lumbosacral radiculopathy

Design
This study is a randomized controlled trial with three parallel groups, double-blind, and phase 2, which will be conducted on 90 patients with lumbosacral radiculopathy at Baghiatallah Hospital. Randomization wil be done with the www.randomization.com website.

Settings and conduct
This prospective study will be conducted on 90 patients with lumbar radiculopathy at Baqiyatallah Hospital. The study follows a double-blind design; both the physician and patient will be unaware of the type of medication.

Participants/Inclusion and exclusion criteria
Inclusion criteria: chronic low back pain for > 12 weeks without motor deficit, failed conservative treatment for > 4 months, Visual analuge score > 4, Oswerty Disability Scale > 45 Exclusion criteria: Low back pain with motor deficit, history of neuropathy, myopathy, motor neuron diseases, rheumatologic diseases, collagenosis, diabetes mellitus, cancer or vertebral fractures, history of epidural injection or placement of epidural catheters, Discogel injection or percutaneous laser disk decompression

Intervention groups
After positioning the patient in the prone position, the sacral hiatus will be identified using both anteroposterior and lateral views with fluoroscopy guidance. A spinal needle will be inserted at the level of the third sacral vertebra. The first group will receive 80 mg of triamcinolone , 2 mg of ropivacaine , and 10 cc of 5% saline. The second group will receive 80 mg of triamcinolone , 2 mg of ropivacaine , and 1500 IU (1 vial) of hyaluronidase. The third group will receive 80 mg of triamcinolone , 2 mg of ropivacaine, 4000 IU of erythropoietin, and 10 cc of 5% saline.

Main outcome variables
Pain (VAS), disability (ODI)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260926071198N1**
Registration date: **2026-10-27, 1405/08/05**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-27, 1405/08/05**
Update count: **0**

Registration date
2026-10-27, 1405/08/05

Registrant information

Name
Reza Yousefvand

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01

Expected recruitment end date
2027-04-21, 1406/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative effectiveness of triamcinolone alone versus triamcinolone and hyaluronidase or triamcinolone with erythropoietin in epidural injections for lumbosacral radiculopathy: A randomized controlled trial

Public title
The comparative efficacy of triamcinolone and combination of triamcinolone and erythropoietin and triamcinolone or triamcinolone and hyaluronidase in epidural injection for lumbosacral radiculopathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age>18 y Body mass index less than 40 kg/m2 Chronic low back pain for more than 12 weeks Unsuccesful conservative treatment for at least 4 months (at least one nonpharmacological and two pharmacological treatment) At least six weeks since the last intramascular corticosteroid injection At least four weaks since the last physiotherapy session Pain levels more than 4 on the visual analog scale Disability score more than 45 on the Oswerty Disability Scale
Exclusion criteria:
Chronic low back pain with motor deficit History of rheumatologic disease, Diabetes and liver disease Cancer Fracture in vertebral body Usage of immunosuppresive drugs Long term use of corticosteroids Uncontroled cardiopulmonary diseases Coagolopathy History of epidural catether placement Allergy to contrast, local steroids or hyaluronidase Pregnancy History of neuropathy, myopathy or motor neuron disease
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to one of three groups: Group A will receive triamcinolone, Group B will receive triamcinolone and erythropoietin, and Group C will receive triamcinolone and hyaluronidase. The randomization process will utilize the website www.randomization.com. A simple randomization method will be employed, with each participant being treated as an individual unit of randomization. After randomization the results will be given to an anesthesiologist assistant who is not involved in this study and is responsible for prepering the injectant. The physical medicine and rehabilitation specialist and the patient will be blinded to the type of drug. The anesthesiologist assistant will open the pocket and prepare the drug outside the operating room. The drug which is same in volume and appearance in all three groups will then be provided for the physician.
Blinding (investigator's opinion)
Double blinded
Blinding description
After randomization the results will be given to an anesthesiologist assistant who is not involved in this study and is responsible for prepering the injectant. The physical medicine and rehabilitation specialist and the patient will be blinded to the type of drug. The anesthesiologist assistant will open the pocket and prepare the drug outside the operating room. The drug which is same in volume and appearance in all three groups will then be provided for the physician.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baghiatollah University of Medical Sciences
Street address
Physical medicine and rehabilitation department, Baghiatollah Hospital, Mollasadra St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435915371
Approval date
2026-08-10, 1405/05/19
Ethics committee reference number
IR.BMSU.BAQ.REC.1405.031

Health conditions studied

1

Description of health condition studied
Lumbosacral radiculopathy
ICD-10 code
G55

ICD-10 code description
Nerve root and plexus compressions in diseases classified elsewhere

Primary outcomes

1

Description
Pain
Timepoint
before intervention and 2 weeks, 3 months and 6 months after intervention
Method of measurement
Visual analouge score

2

Description
Disability
Timepoint
before intervention and 2 weeks, 3 months and 6 months after intervention
Method of measurement
Oswerthy Disability Scale

Secondary outcomes

1

Description
Frequency of analgesic use per week
Timepoint
before epidural injection, 2 weeks, 3 months and 6 months after epidural injection
Method of measurement
Check list

2

Description
Need for medication to initiate sleep
Timepoint
before epidural injection, 2 weeks, 3 months and 6 months after epidural injection
Method of measurement
Check list

Intervention groups

1

Description
Control Group: After positioning the patient in the prone position, the sacral hiatus will be located using fluoroscopy guidance in both anteroposterior and lateral views. Under sterile conditions, 2 ml of 2% lidocaine will be injected for local anesthesia. An 18-gauge spinal needle will then be inserted, positioning the tip at the third sacral vertebra. The correct placement will be confirmed using fluoroscopy guidance. Following this, the following materials will be injected: 80 mg of triamcinolone (2 cc), 2 mg of ropivacaine (10 cc), and 10 cc of 5% saline.
Category
Treatment - Drugs

2

Description
Intervention group: After positioning the patient in the prone position, the sacral hiatus will be located using fluoroscopy guidance in both anteroposterior and lateral views. Under sterile conditions, 2 ml of 2% lidocaine will be injected for local anesthesia. An 18-gauge spinal needle will then be inserted, positioning the tip at the third sacral vertebra. The correct placement will be confirmed using fluoroscopy guidance. Following this, the following materials will be injected: 80 mg of triamcinolone (2 cc), 2 mg of ropivacaine (10 cc), and 1500 IU hyaluronidase diluted in 10cc of 5% saline.
Category
Treatment - Drugs

3

Description
Intervention group: After positioning the patient in the prone position, the sacral hiatus will be located using fluoroscopy guidance in both anteroposterior and lateral views. Under sterile conditions, 2 ml of 2% lidocaine will be injected for local anesthesia. An 18-gauge spinal needle will then be inserted, positioning the tip at the third sacral vertebra. The correct placement will be confirmed using fluoroscopy guidance. Following this, the following materials will be injected: 80 mg of triamcinolone (2 cc), 2 mg of ropivacaine (10 cc), and 4000 IU erythropoitin diluted in 10cc of 5% saline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghiatollah hospital
Full name of responsible person
Reza Yousefvand
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Reza Yousefvand
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Rehabilitation management
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Latest degree
Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All gathered datas will be available for reseachers after emitting the name of the patients. Researchers can contact us at jusef.yvd@gmail.com.

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
Only available for people working in academic institutions.

Under which criteria data/document could be used
Only available for people working in academic institutions. Using data in review articles is allowed.

From where data/document is obtainable
All gathered datas will be available for reseachers after emitting the name of the patients. Researchers can contact us at jusef.yvd@gmail.com.

What processes are involved for a request to access data/document
All gathered datas will be available for reseachers after emitting the name of the patients. Researchers can contact us at jusef.yvd@gmail.com. The information will be provided for researchers in aproximatly 2 weeks.

Comments