Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the efficacy of transforaminal epidural steroid combined hyaluronic acid versus steroid combined hyaluronidase injection in improvement of function and pain related to lumbosacral disk herniation, A Randomized Clinical Trial

Protocol summary

Study aim
Comparing the effectiveness of transforaminal epidural steroid-hyaluronic acid injection with steroid-hyaluronidase in pain control and functional improvement in patients with lumbar radiculopathy

Design
This study is a double-blind clinical trial. 17 patients are enrolled in each group. Phase 3 is performed on 34 patients. The sorting process is such that the type of treatment is provided to the patient in a coded form in opaque sealed envelopes by a third person outside the research team (ward secretary) on the day of injection, depending on the patient's referral.

Settings and conduct
This is done in Shahid Modarres Hospital, in the operating room, under sterile conditions under fluoroscopy guidance. On the day of the injection, patients give the envelope they received from the secretary of the operating room to the operating room doctor. By opening the envelope in the operating room, the doctor becomes aware of the type of substance the patient is injecting and will administer the injection to the patient. In this study, the patient and the outcome assessor will be blinded and will not know the type of substance injected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with lumbar disc herniation with pain radiating to the lower extremities. Exclusion criteria: Progressive neurological deficit and cauda equina syndrome.

Intervention groups
Group 1: Combination of 40 mg methylprednisolone , 2 cc of low molecular weight hyaluronic acid (20 mg/2 ml) . Group 2: 40 mg methylprednisolone, 2 cc of hyaluronidase (1500 unit vial diluted in 6 cc and 2 cc of it injected) injected transforaminally.

Main outcome variables
Pain assessment and functional improvement

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130523013442N39**
Registration date: **2026-05-11, 1405/02/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-11, 1405/02/21**
Update count: **0**

Registration date
2026-05-11, 1405/02/21

Registrant information

Name
Seyed Ahmad Raeissadat
Name of organization / entity
Modares Hospital
Country
Iran (Islamic Republic of)
Phone
+98 21 2273 1112
Email address
a_raeissadat@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-04-21, 1405/02/01
Expected recruitment end date
2026-09-22, 1405/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the efficacy of transforaminal epidural steroid combined hyaluronic acid versus steroid combined hyaluronidase injection in improvement of function and pain related to lumbosacral disk herniation, A Randomized Clinical Trial

Public title
Comparing the efficacy of transforaminal epidural steroid combined hyaluronic acid versus steroid combined hyaluronidase injection in improvement of function and pain related to lumbosacral disk herniation, A Randomized Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients aged 20 to 65 years with a BMI <33 with radicular back pain of lumbar disc origin that has not responded to conservative treatments within 6 weeks of treatment. Positive MRI findings of intervertebral disc herniation and canal stenosis or intervertebral foramen stenosis and positive clinical tests in favor of intervertebral disc involvement and lumbar root involvement in EMG/NCS
Exclusion criteria:
Neurological deficits such as muscle weakness or symptoms of cauda equina syndrome, multi-root and bilateral involvement, bone stenosis and stenosis due to ligamentous hypertrophy, history of back surgery, vascular problems of the lower extremities and vascular claudication, history of lower extremities surgery, unstable hemodynamic conditions, sensitivity to drugs used in the study, use of corticosteroids (last 2 weeks), presence of coagulation disorders or uncontrolled systemic problems, uncontrolled diabetes, uncontrolled blood pressure, presence of systemic infection or infection at the injection site, pregnancy, presence of neurological diseases such as MS.
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two groups: steroid-hyaluronic acid injection and steroid-hyaluronidase injection in a one-to-one ratio. The selection process is as follows: the type of treatment is coded in opaque envelopes and provided to the patient by a third person outside the research team (ward secretary) on the day of the injection, based on the patient's visit. The patient hands the envelope to the performing physician in the operating room, and the type of injection will be performed for the patient based on the code specified in the envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
The type of treatment is coded in opaque sealed envelopes and provided to the patient by a third party outside the research team (ward secretary) on the day of the injection, based on the patient's visit. The patient hands the envelope to the performing physician in the operating room, and the type of injection will be administered to the patient based on the code specified in the envelope.
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
Tehran - Yadegar Imam Highway (RAH) - Saadat Abad Intersection - Shahid Modarres Hospital
City
tehran
Province
Tehran
Postal code
1998734383
Approval date
2026-02-08, 1404/11/19
Ethics committee reference number
IR.SBMU.RETECH.REC.1404.1088

Health conditions studied

1

Description of health condition studied
lumbar disc herniation and lumbar spinal stenosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Timepoint
Method of measurement

2

Description
pain and function
Timepoint
Before the intervention, 1 month, 3 months and 6 months after the intervention
Method of measurement
Pain assessment with visual analog scale, function assessment with Roland-Morris questionnaire and Oswestry Disability Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: steroid-hyaluronic-acid, control group:steroid-hyaluronidase
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
shahid modarres hospital
Full name of responsible person
seyed Ahmad Raeissadat
Street address
Yadgar Imam Highway, Saadat Abad Intersection
City
tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2236 0635
Email
ahmad_raeissadat@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
afshin zarghi
Street address
Velenjak, Daneshjoo Boulevard, Arabi Street, Shahid Beheshti University of Medical Sciences
City
tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9788
Email
sci@sbmu.ac.ir
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
seyed Ahmad Raeissadat
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Physical Medicine
Street address
Yadgar Imam Highway, Saadat Abad Intersection
City
tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2236 0635
Email
ahmad_raeissadat@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Amir hossein Mahdi kaghazi

Position
Fellowship Assistant

Latest degree
Specialist

Other areas of specialty/work
Physical Medicine

Street address
Intersection of Yadgar-e-Imam and Saadat Abad Highways, Shahid Modarres Hospital

City
tehran

Province
Tehran

Postal code
1998734383

Phone
+98 21 2236 0635

Email
amirhosseinkaghazi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Amir hossein Mahdi kaghazi

Position
Fellowship Assistant

Latest degree
Specialist

Other areas of specialty/work
Physical Medicine

Street address
Intersection of Yadgar-e-Imam and Saadat Abad Highways, Shahid Modarres Hospital

City
tehran

Province
Tehran

Postal code
1998734383

Phone
+98 21 2236 0635

Email
amirhosseinkaghazi@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available