Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Ultrasound-Guided PRP Injection Versus Corticosteroid Injection on Pain Relief and Functional Improvement in Patients with Low Back Pain due to Lumbar Facet Joint Involvement: A Double-Blind, Non-Inferiority Clinical Trial

Protocol summary

Study aim

Evaluation and comparison of the effects of PRP and corticosteroid injections on pain reduction and functional improvement in patients with lumbar facet joint syndrome, using the Visual Analog Scale, Oswestry Disability Index, and Roland–Morris Disability Questionnaire at baseline, 1 month, and 3 months after the intervention

Design

A Phase III randomized, double-blind, controlled clinical trial with parallel groups, conducted on 30 patients. Restricted randomization (block randomization) was used for allocation, and random number–generation software such as R was employed to randomly select the generated blocks

Settings and conduct

After obtaining informed consent, patients are randomly assigned to two groups: A (triamcinolone) and B (PRP). VAS, ODI & RDQ assessments are performed at baseline and at 1 and 3 months after the intervention. Periarticular injection of the affected lumbar facet joint is performed by a specialist in Physical Medicine and Rehabilitation at Shariati Hospital, Tehran, under ultrasound guidance. Blinding is ensured by uniform blood sampling, prone-position injections, and identical injection volume and technique, with data analyzed using coded groups (A/B) to maintain analyst blinding.

Participants/Inclusion and exclusion criteria

Adults 18–65 years with chronic low back pain (>3 months), VAS >4, failure of conservative treatment, normal lower limb strength, unilateral lumbar facet–origin pain, and single-level facet involvement are included; those outside this age range, with pain <3 months, VAS ≤4, lower limb weakness, or multilevel facet involvement are excluded.

Intervention groups

A(Control): Periarticular injection of 1 mL triamcinolone (40 mg) combined with 2 mL of 2% lidocaine B: Periarticular injection of 2.5 mL platelet-rich plasma combined with 0.5 mL of 2% lidocaine

Main outcome variables

Pain intensity, functional disability, physical disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180804040685N6**
Registration date: **2026-01-19, 1404/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-19, 1404/10/29**
Update count: **0**

Registration date

2026-01-19, 1404/10/29

Registrant information

Name

Hamid Reza Fateh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-05, 1404/10/15

Expected recruitment end date

2026-10-07, 1405/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Ultrasound-Guided PRP Injection Versus Corticosteroid Injection on Pain Relief and Functional Improvement in Patients with Low Back Pain due to Lumbar Facet Joint Involvement: A Double-Blind, Non-Inferiority Clinical Trial

Public title

Effect of PRP injection on low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic low back pain lasting more than 3 months Pain score greater than 4 on the visual analog scale (VAS > 4) Inadequate response to noninvasive and conservative treatments such as nonsteroidal anti-inflammatory drugs (NSAIDs) and physical therapy based on the patient's medical history Normal lower limb muscle strength on neurological examination Unilateral lumbar facet joint pain Local tenderness on physical examination over the facet joint and pain elicited during lumbar hyperextension maneuvers Single-level involvement of the facet joint

Exclusion criteria:

Age younger than 18 years or older than 65 years Acute low back pain with a duration of less than 3 months Pain score of 4 or ≤4 on the Visual Analog Scale Abnormal lower extremity muscle strength on neurological examination Involvement of more than one facet joint (multi-level involvement)

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use restricted randomization, specifically block randomization, in this study. Blocking is commonly used to achieve balance in the number of participants allocated to each study group. This feature helps researchers ensure equal group sizes, particularly when interim analyses are required during the sampling process. All blocks will be of equal size, and in this two-arm trial we will have three blocks of size 10, each consisting of 5 participants in the intervention group and 5 participants in the control group. Random selection of the generated blocks will be performed using random number–generation software such as R, and three random numbers from 1 to 3 will be generated to select the blocks. For allocation concealment, we will use allocation concealment, which refers to the method used to implement the random sequence among study participants in such a way that the assigned group is not known prior to allocation. This will be achieved using sequentially numbered, sealed, opaque envelopes (SNOSE). In this method, each generated random sequence is recorded on a card, and the cards are placed sequentially inside envelopes. To preserve the random sequence, the envelopes are numbered in the same order on their outer surface. The envelopes are then sealed and placed sequentially in a box. At the start of participant enrollment, based on the order of entry of eligible participants into the study, the envelopes are opened sequentially, and the allocated group for each participant is then revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind randomized clinical trial with two parallel groups, in which both the patients and the data analyst are blinded to group allocation. To ensure patient blinding, blood samples will be taken from all patients (with a smaller volume drawn from the corticosteroid group), and all patients will receive the injection in the prone position. Patients will remain unaware of the substance being injected. To maintain blinding of the analyst—who is an individual other than the physician/investigator and the data collection personnel—the data will be provided for analysis coded only as Group A and Group B, without revealing the actual group assignments.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shariati Hospital, Tehran University of Medical Sciences

Street address

Jalal aleahmad Highway

City

Tehran

Province

Tehran

Postal code

1417863181

Approval date

2025-12-08, 1404/09/17

Ethics committee reference number

IR.TUMS.SHARIATI.REC.1404.125

Health conditions studied

1

Description of health condition studied

Low Back Pain due to Lumbar Facet Joint Involvement

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain intensity

Timepoint

Measurement of pain intensity at baseline (before the intervention) and at 30 and 90 days after initiation of the intervention

Method of measurement

Visual Analog Scale

2

Description

Functional disability

Timepoint

Measurement of functional disability at baseline (before the intervention) and at 30 and 90 days after initiation of the intervention

Method of measurement

Oswestry Disability Index

3

Description

Physical disability

Timepoint

Measurement of physical disability at baseline (before the intervention) and at 30 and 90 days after initiation of the intervention

Method of measurement

Roland-Morris Disability Questionnaire

Secondary outcomes

1

Description

Analgesic medication use

Timepoint

During the 3-month follow-up period

Method of measurement

Daily medication diary

2

Description

Adverse events and safety

Timepoint

During the 3-month follow-up period

Method of measurement

Adverse Event Checklist

3

Description

Need for additional treatments or surgical intervention

Timepoint

During the 3-month follow-up period

Method of measurement

Regular monitoring and follow-up visits by the physician/investigator

Intervention groups

1

Description

Intervention group: Initially, approximately 15 mL of peripheral venous blood will be collected from each patient using a blood collection set and sterile syringes containing an anticoagulant. The sample will be immediately centrifuged for 5 minutes at 3200 rpm. An Alpha kit will be used in this process, yielding platelet-rich plasma (PRP) with a concentration of approximately five times the baseline platelet level. Each patient will receive an injection of 2.5 mL of autologous PRP, prepared from their own peripheral blood, combined with 0.5 mL of lidocaine (to reduce procedural pain and improve patient comfort), for a total volume of 3 mL. The injection technique, volume, site, and procedural conditions will be identical to those of the control group to ensure comparable patient experience and to control for the placebo effect. The injection will be administered periarticularly into the lumbar facet joint using a spinal needle under ultrasound guidance, performed by an experienced specialist in Physical Medicine and Rehabilitation. Only one injection session will be performed.

Category

Treatment - Drugs

2

Description

Control group: Initially, approximately 5 mL of peripheral venous blood will be collected from each patient using a blood collection set and sterile syringes containing an anticoagulant and sent to the laboratory for complete blood count (CBC) testing for ethical reasons and to maintain blinding. In this group, a periarticular corticosteroid injection consisting of triamcinolone 40 mg (1 mL) combined with 2 mL of 2% lidocaine (to reduce procedural pain and improve patient comfort), for a total volume of 3 mL, will be administered. The injection technique, volume, site, and procedural conditions will be identical to those of the intervention group to ensure

a comparable subjective experience and to control for the placebo effect. The injection will be performed periarticularly into the lumbar facet joint using a spinal needle under ultrasound guidance, by an experienced specialist in Physical Medicine and Rehabilitation. Only one injection session will be performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati hospital

Full name of responsible person
Hamid Reza Fateh

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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?
No

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

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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Position
Resident

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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
No - There is not 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