# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Sep 2026

# Efficacy of Intramuscular Platelet-Rich Plasma Versus Ultrasound-Guided Ozone Injection into the Multifidus Muscle forSymptom Control in Patients with Chronic Non-Specific Low Back Pain: A Randomized Clinical Trial

## Protocol summary

**Study aim**

مقایسه اثربخشی تزریق داخل عضلانی پلاسمای غنی از پلاکت در برابر تزریق اوزون تحت هدایت سونوگرافی به عضله مولتی‌فیدوس برای کنترل علائم در بیماران مبتلا به کمردرد مزمن غیراختصاصی.

**Design**

Randomized, parallel-group, single-blind (assessor-blind), two-arm superiority trial with 60 patients (30 per arm). Allocation concealed via sequentially numbered opaque sealed envelopes. Randomization uses variable blocks of 4 and 6 generated with R software.

**Settings and conduct**

Single-center study at the Sports and Exercise Medicine outpatient clinic of Hazrat-e Rasool General Hospital, Iran University of Medical Sciences. After baseline assessment and concealed allocation, patients receive two ultrasound-guided injections into the multifidus muscle two weeks apart. The outcome assessor and data analyst are blinded to group assignment.

**Participants/Inclusion and exclusion criteria**

Inclusion: age 18–65; chronic non-specific low back pain lasting ≥3 months; baseline pain ≥4 on VAS; failed 6-week conservative treatment. Exclusion: specific spinal pathology (radiculopathy, stenosis, fracture, infection, tumor); red flags; prior lumbar surgery; recent spinal injections; coagulation disorders; pregnancy; systemic corticosteroid use.

**Intervention groups**

Intervention group 1: Two sessions of intramuscular autologous PRP injection (platelet concentration 3–5 times baseline) into the multifidus muscle at L4–L5, 2 weeks apart. Intervention group 2: Two sessions of intramuscular oxygen–ozone injection (20 mcg/mL) into the same muscle at the same level and interval. All injections are performed under real-time ultrasound guidance using a multi-site peppering technique.

**Main outcome variables**

Change in low back pain intensity measured by Visual Analog Scale (0–10) from baseline to 6 months after the intervention.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20140907019073N9**
Registration date: **2026-08-08, 1405/05/17**
Registration timing: **prospective**

Last update: **2026-08-08, 1405/05/17**
Update count: **0**

**Registration date**

2026-08-08, 1405/05/17

**Registrant information**

**Name**
Ali Mazaherinezhad
**Name of organization / entity**
IUMS
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 6435 2446
**Email address**
mazaherinezhad.a@iums.ac.ir

**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-09-06, 1405/06/15

**Expected recruitment end date**

2028-03-20, 1407/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy of Intramuscular Platelet-Rich Plasma Versus Ultrasound-Guided Ozone Injection into the Multifidus Muscle forSymptom Control in Patients with Chronic Non-Specific Low Back Pain: A Randomized Clinical Trial

**Public title**

Comparison of PRP and Ozone Injection for Chronic Non-Specific Low Back Pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age between 18 and 65 years Chronic non-specific low back pain lasting at least 3 months Presence of mechanical pain in the lumbar region without clinical evidence of specific causes of low back pain Pain intensity of at least 4 on the Visual Analog Scale (VAS) at the time of study entry Inadequate response to conservative treatments including medication, physiotherapy, exercise therapy, or activity modification during at least the past 6 weeks Ability to cooperate and complete all clinical and functional assessments used in the study Signing the written informed consent form to participate in the study

**Exclusion criteria:**

Presence of specific causes of low back pain including symptomatic disc herniation with radiculopathy, spinal canal stenosis, unstable spondylolisthesis, fracture, infection, tumor, or inflammatory spinal diseases Presence of Red Flags including unexplained weight loss, fever, history of malignancy, progressive neurological deficit, or cauda equina syndrome History of lumbar spine surgery History of PRP, ozone, or other therapeutic injections in the lumbar region during the past six months Neurological or musculoskeletal diseases affecting spinal and lower limb function Active rheumatologic diseases or uncontrolled systemic diseases Coagulation disorders or use of anticoagulant medications that cannot be temporarily discontinued Presence of active local or systemic infection at the time of injection Pregnancy or breastfeeding Known sensitivity to blood products or impossibility of PRP preparation Systemic corticosteroid use during the past three months Inability to follow up regularly, lack of cooperation in assessments, or voluntary withdrawal from the study at any stage

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization sequence will be generated by an independent researcher who is not involved in participant recruitment, treatment, or outcome assessment. The allocation sequence will be created using the statistical software R (version 4.5) with a random number generation algorithm. Block randomization with randomly varying block sizes of four and six will be applied to ensure balanced group sizes throughout the trial. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes (SNOSE). After a participant completes all baseline assessments, the corresponding envelope will be opened by a designated staff member to reveal the group assignment.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This trial is designed as a single-blind study. The outcome assessor and the data analyst will be blinded to the participants' group allocation throughout the study period and data analysis. Blinding will be maintained by using coded group labels in all study forms and databases, without revealing the actual treatment received. The physician performing the injections cannot be blinded due to the obvious differences in the preparation and nature of the two injectates (autologous platelet-rich plasma versus medical oxygen-ozone gas mixture). Participants will also be aware of their treatment group for the same reason; however, they will be instructed not to disclose this information to the assessor.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

This is a randomized, single-blind (assessor-blind), parallel-group, two-arm clinical trial. Two injection sessions are administered two weeks apart, both under real-time ultrasound guidance targeting the multifidus muscle at the L4–L5 level. A multi-site peppering technique is used for uniform distribution of the injectate. No stratification is applied.

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Iran University of Medical

Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Next to Milad Tower, Central Library Building, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2026-07-19, 1405/04/28

**Ethics committee reference number**

IR.IUMS.FMD.REC.1405.364

## Health conditions studied

### 1

**Description of health condition studied**

Chronic Non-Specific Low Back Pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain (M54.5)

## Primary outcomes

### 1

**Description**

Change in low back pain intensity from baseline to 6 months after the intervention, measured by the Visual Analog Scale (0 to 10).

**Timepoint**

At baseline (before intervention) and at 6 months after the intervention.

**Method of measurement**

Visual Analog Scale, a 10-centimeter horizontal line where 0 indicates no pain and 10 indicates the worst pain imaginable. The patient marks the line to indicate their current pain intensity, and the distance from zero is recorded in centimeters.

## Secondary outcomes

### 1

**Description**

Change in functional disability measured by the Oswestry Disability Index (ODI) from baseline to 6 months after intervention.

**Timepoint**

Baseline, 1 month, 3 months, and 6 months after intervention.

**Method of measurement**

Oswestry Disability Index (ODI) questionnaire, a 10-item tool evaluating pain-related disability in daily activities. Total score ranges from 0% (no disability) to 100% (maximum disability).

### 2

**Description**

Change in health-related quality of life measured by the EQ-5D-5L questionnaire from baseline to 6 months.

**Timepoint**

Baseline, 1 month, 3 months, and 6 months.

**Method of measurement**

EuroQol Five-Dimension Five-Level (EQ-5D-5L) questionnaire assessing mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

### 3

**Description**

Change in lumbar flexion range of motion measured by the Modified Schober test from baseline to 6 months.

**Timepoint**

Baseline, 1 month, 3 months, and 6 months.

**Method of measurement**

Modified Schober test: a 15 cm distance between two skin marks over the lumbar spine is measured in upright standing and again after maximal forward bending. The difference is recorded in centimeters.

### 4

**Description**

Change in trunk extensor muscle endurance measured by the Biering-Sorensen test from baseline to 6 months.

**Timepoint**

Baseline, 1 month, 3 months, and 6 months.

**Method of measurement**

Biering-Sorensen test: the time (in seconds) the patient can maintain the unsupported upper body in a horizontal prone position.

### 5

**Description**

Change in physical function measured by the Five Times Sit-to-Stand test (5xSTS) from baseline to 6 months.

**Timepoint**

Baseline, 1 month, 3 months, and 6 months.

**Method of measurement**

Time (in seconds) required to complete five consecutive sit-to-stand repetitions from a standard chair.

### 6

**Description**

Patient-perceived global improvement measured by the Global Rating of Change scale at 1, 3, and 6 months.

**Timepoint**

1 month, 3 months, and 6 months after intervention (no baseline value).

**Method of measurement**

15-point Global Rating of Change scale ranging from -7 (a very great deal worse) to +7 (a very great deal better).

### 7

**Description**

Frequency of analgesic medication use during follow-up.

**Timepoint**

Recorded at baseline, 1 month, 3 months, and 6 months.

**Method of measurement**

Self-reported number of analgesic medication doses per week.

### 8

**Description**

Patient satisfaction with the received treatment at follow-up points.

**Timepoint**

1 month, 3 months, and 6 months after intervention.

**Method of measurement**

5-point Likert scale (very dissatisfied, dissatisfied, neutral, satisfied, very satisfied).

### 9

**Description**

Incidence of treatment-related adverse events throughout the study period.

**Timepoint**

Continuous monitoring from baseline through 6-month follow-up

**Method of measurement**

Systematic recording of any adverse events (local pain, swelling, hematoma, infection, symptom exacerbation, etc.) in a dedicated form.

### 10

**Description**

Change in low back pain intensity from baseline to 1 month after the intervention, measured by the Visual Analog Scale.

**Timepoint**

Baseline and 1 month after intervention.

**Method of measurement**

Visual Analog Scale (0–10 cm), as described for the primary outcome.

### 11

**Description**

Change in low back pain intensity from baseline to 3 months after the intervention, measured by the Visual Analog Scale.

**Timepoint**

Baseline and 3 months after intervention.

**Method of measurement**

Visual Analog Scale (0–10 cm), as described for the primary outcome.

## Intervention groups

### 1

**Description**

Intervention group 1: Two sessions of intramuscular injection of autologous platelet-rich plasma (PRP) into the multifidus muscle at the L4–L5 level, 2 weeks apart. For each session, 40 mL of peripheral venous blood is drawn and processed with a double-centrifugation protocol (10 minutes at 1600 rpm, then 6 minutes at 3500 rpm) to yield approximately 5 mL of PRP with a platelet concentration 3–5 times that of whole blood. Injections are performed bilaterally under real-time ultrasound guidance using a 23-gauge needle and a multi-site peppering technique (4 functional points per side) to ensure uniform distribution within the muscle belly.

**Category**

Treatment - Other

### 2

**Description**

Intervention group 2: Two sessions of intramuscular injection of medical oxygen–ozone mixture into the multifidus muscle at the L4–L5 level, 2 weeks apart. The gas mixture is prepared using a standard medical ozone generator at a concentration of 20 micrograms per milliliter. A total volume of 20 milliliters (5 mL per functional point) is injected bilaterally per session. Injections are performed under real-time ultrasound guidance with a 23-gauge needle and the identical multi-site peppering technique (4 points per side) as in the PRP group.

**Category**

Treatment - Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Rasool Akram Hospital

**Full name of responsible person**

Ali Mazaherinezhad

**Street address**

Maziar Mansouri, StreetSattar Khan Street, Rasool Akram Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 2446

**Email**

mazaherinezhad@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Ali Javad Moosavi

**Street address**

Iran University of Medical sciences, south side of Hemmat highway, Tehran, Iran.

**City**
Tehran

**Province**
Tehran

**Postal code**
1449614535

**Phone**
+98 21 8670 2030

**Email**
intl@iums.ac.ir

**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

**Contact**

**Name of organization / entity**
Iran University of Medical Sciences

**Full name of responsible person**
Dr.Ali Mazaherinezhad

**Position**
Sports medicine specialist

**Latest degree**
Specialist

**Other areas of specialty/work**
Sport Medicine

**Street address**
Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

**City**
Tehran

**Province**
Tehran

**Postal code**
1449614535

**Phone**
+98 21 6435 2446

**Fax**

**Email**
Mazaherinezhad@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Iran University of Medical Sciences

**Full name of responsible person**
Ali Mazaherinezhad

**Position**
Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Sport Medicine

**Street address**
Hazrate-rasool-Hospital

**City**
Tehran

**Province**
Tehran

**Postal code**
1449614535

**Phone**
+98 21 6435 2446

**Fax**
+98 21 6650 9108

**Email**
mazaherinezhad.a@iums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Iran University of Medical Sciences

**Full name of responsible person**
Ali Mazaherinezhad

**Position**
Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Sport Medicine

**Street address**
Hazrate-rasool-Hospital

**City**
Tehran

**Province**
Tehran

**Postal code**
1449614535

**Phone**
+98 21 6435 2446

**Fax**
+98 21 6650 9108

**Email**
mazaherinezhad.a@iums.ac.ir

## 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

De-identified individual participant data (IPD), study protocol, statistical analysis plan (SAP), data dictionary, analysis code (R scripts), and the informed consent form will be available. All shared datasets will be fully de-identified to protect participant confidentiality.

**When the data will become available and for how long**

Beginning 6 months after publication of the primary study results and available for 5 years.

**To whom data/document is available**

Qualified researchers affiliated with academic or research institutions whose proposed use has been approved by the principal investigator.

**Under which criteria data/document could be used**

Data may be used only for scientifically sound secondary analyses after submission of a research proposal and approval by the principal investigator. Users must agree not to attempt participant re-identification and must comply with applicable ethical regulations.

**From where data/document is obtainable**

Requests should be sent to the Principal Investigator via the corresponding author's institutional email address.

**What processes are involved for a request to access data/document**

Requests will be reviewed by the study investigators within approximately four weeks. Approved applicants will receive the requested materials after signing a data sharing agreement, if applicable.

**Comments**