Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of corticosteroids and PRP on the treatment of mild to moderated knee osteoarthritis: A duble blinded randomized clinical trial

Protocol summary

Study aim
Comparison of the Effects of PRP and Corticosteroid on the Treatment of Knee Osteoarthritis

Design
A total of 44 knees from 22 patients with mild to moderate knee osteoarthritis will be randomly allocated to one of two intra-articular injection groups: corticosteroid or PRP. At the end of the second, fourth, and sixth months after treatment, the patients will be evaluated for osteoarthritis-related outcomes and knee injuries using the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire.

Settings and conduct
Therefore, the patient and the outcome assessor will remain unaware of the type of injection administered until the patients' pain scores have been assessed and the data have been analyzed. Finally, to ensure blinding of the individual responsible for data analysis, the study arms will be entered into the software using the codes A and B, and the coded data will be provided to the analyst for statistical analysis.

Participants/Inclusion and exclusion criteria
Patients over 50 years of age with mild to moderate knee osteoarthritis.

Intervention groups
One group receiving intra-articular corticosteroid injection and one group receiving intra-articular PRP injection.

Main outcome variables
Assessment and comparison of pain, activities of daily living, sports and recreational activities, quality of life, joint stiffness, and knee discomfort between the two groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260924071177N1**
Registration date: **2026-09-28, 1405/07/06**
Registration timing: **prospective**

Last update: **2026-09-28, 1405/07/06**
Update count: **0**

Registration date
2026-09-28, 1405/07/06

Registrant information

Name
Behzad Xeyati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3264 0020

Email address
bahoooz.649@gmail.com

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-11-22, 1405/09/01

Expected recruitment end date
2027-11-22, 1406/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effects of corticosteroids and PRP on the

treatment of mild to moderated knee osteoarthritis: A duble blinded randomized clinical trial

Public title
Compairing the effects of corticosteroids and PRP on treatment of knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 50 years Morning stiffness lasting less than 30 minutes Crepitus during active knee movement Bony tenderness Bony enlargement Absence of evidence of septic arthritis of the knee
Exclusion criteria:
History of rheumatoid arthritis Evidence of septic arthritis History of intra-articular injection within the previous 6 months Any hematological disorder, including coagulopathy Injection phobia History of severe knee trauma Grade 3 osteoarthritis
Age
From **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **22**
More than 1 sample in each individual
Number of samples in each individual: **2**
In each patient, one knee will receive PRP injection, while the contralateral knee will receive corticosteroid injection.
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients will be randomly allocated to the intervention groups using a permuted block randomization method with a block size of 4. Accordingly, four slips of paper of equal size and color will be prepared, with the letter A written on two of them and the letter B written on the other two. This method is similar to sampling without replacement. Upon enrollment of each eligible patient, one slip will be randomly selected. If the selected slip bears the letter A, the patient will be assigned to the PRP injection group, whereas if it bears the letter B, the patient will be assigned to the corticosteroid injection group. After a slip is selected, it will be removed from the pool, leaving three slips to randomly determine the treatment allocation of the next three eligible patients. At the end of each block, two patients will have been allocated to the PRP group and two patients to the corticosteroid group, thereby ensuring an equal sample size in the two treatment groups. This procedure will continue until the required sample size is reached, with patients being allocated equally to the two treatment groups under investigation.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted using a double-blind design. Accordingly, the individual responsible for assessing the outcomes of osteoarthritis and knee injuries at the second and sixth months after treatment, as well as the patient and, ultimately, the individual responsible for data analysis, will be blinded to the type of injection administered to each knee. Specifically, they will be unaware of which knee received PRP and which knee received corticosteroid. To blind the patients and the outcome assessor, PRP and corticosteroid will be drawn into identical syringes by a nurse and labeled with codes before being provided to the surgeon for injection. Therefore, the patient and the outcome assessor will remain unaware of the type of injection administered until the pain scores and other outcome measures have been assessed. Finally, to blind the data analyst, the treatment arms will be entered into the software using codes A and B, and the coded dataset will be provided to the analyst for statistical analysis. Thus, the data analyst will remain unaware of the actual treatment allocation during the analysis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Hamadan University of Medical Sciences
Street address
Hamadan, Shahid Beheshti Boulevard, Besat Hospital
City
Hamedan
Province
Hamadan
Postal code
6514845411
Approval date
2026-09-12, 1405/06/21
Ethics committee reference number
IR.UMSHA.REC.1405.457

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Pain score in patients with osteoarthritis, assessed using the KOOS questionnaire.

Timepoint

The effects of intra-articular corticosteroid and PRP injections at baseline and at the end of the second, fourth, and sixth months after injection.

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire

2

Description

Activities of Daily Living (ADL) Score Assessed Using the KOOS Questionnaire

Timepoint

The effects of intra-articular corticosteroid and PRP injections at baseline and at the end of the second, fourth, and sixth months after injection.

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire

3

Description

Sport and Recreation Function Score in Patients with Osteoarthritis Assessed Using the KOOS Questionnaire

Timepoint

The effects of intra-articular corticosteroid and PRP injections at baseline and at the end of the second, fourth, and sixth months after injection.

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire

4

Description

Knee-Related Quality of Life (QoL) Score Assessed Using the KOOS Questionnaire

Timepoint

The effects of intra-articular corticosteroid and PRP injections at baseline and at the end of the second, fourth, and sixth months after injection.

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire

5

Description

Knee Stiffness Score Assessed Using the KOOS Questionnaire

Timepoint

The effects of intra-articular corticosteroid and PRP injections at baseline and at the end of the second, fourth, and sixth months after injection.

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire

6

Description

Knee Symptoms Score in Patients with Osteoarthritis Assessed Using the KOOS Questionnaire

Timepoint

The effects of intra-articular corticosteroid and PRP injections at baseline and at the end of the second, fourth, and sixth months after injection.

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention Group: Participants in the first intervention group will receive a single intra-articular injection of 8 mg dexamethasone (corticosteroid) under sterile conditions.

Category

Treatment - Drugs

2

Description

Second Intervention Group: Participants in the second intervention group will receive a single intra-articular injection of platelet-rich plasma (PRP) under sterile conditions. Briefly, 18 mL of peripheral venous blood will be collected from each participant and transferred into two sterile vacuum tubes, each containing 1 mL of anticoagulant. The blood samples will initially be centrifuged at 2,500 rpm for 10 minutes. Subsequently, the samples will undergo a second centrifugation at 1,500 rpm for 10 minutes. Following the second centrifugation step, approximately 3 mL of pure platelet-rich plasma (PRP) will be obtained and administered as a single intra-articular injection under sterile conditions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital

Full name of responsible person
Behzad Xeyati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Mohamad Babamiri

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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Behzad Xeyati

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

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Person responsible for updating data

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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 plan to share or disseminate the de-identified individual participant data after completion of this study. The data will be used solely for research purposes, statistical analysis, and reporting of the study results. The confidentiality of participants' information will be maintained in accordance with ethical principles.
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