Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Hyaluronic Acid injection with and without corticosteroids on the severity of pain and physical function in patients with knee Osteoarthritis grade 2 and 3

Protocol summary

Study aim
To investigate changes in bone pain intensity, improvement in physical function due to knee osteoarthritis after treatment compared to before treatment in recipients of hyaluronic acid alone compared to recipients of corticosteroids + hyaluronic acid.

Design
A clinical trial with a control and intervention group, double-blind, on 88 patients, randomization with a sealed envelope.

Settings and conduct
Participants at Imam Hossein Hospital will be randomly assigned to 2 groups: 1) hyaluronic acid injection alone and 2) hyaluronic acid and corticosteroid combination injection. After patient preparation and local anesthesia, the injection will be performed by a pain specialist using an inferomedial method under ultrasound guidance, with an 18-gauge green needle in the knee joint.

Participants/Inclusion and exclusion criteria
Inclusion: Patients with grade 2 and 3 knee osteoarthritis who are candidates for therapeutic interventions for pain control and referred to the pain clinic of Imam Hossein Hospital. Exclusion: Patients with bone malignancies, drug addicts, history of allergy to hyaluronic acid or corticosteroid drugs, patient dissatisfaction

Intervention groups
Control group 1: Injection of 40 mg of hyaluronic acid alone in the knee joint from the brand Rodiyax-C Target intervention group: Injection of 44 mg of hyaluronic acid and 9 mg of triamcinolone in the knee joint from the brand Rodiyax -T

Main outcome variables
Pain measurement with VAS and physical dysfunction with The Western Ontario and McMaster Universities Osteoarthritis Index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210415050983N11**
Registration date: **2025-06-06, 1404/03/16**
Registration timing: **prospective**

Last update: **2025-06-06, 1404/03/16**
Update count: **0**

Registration date
2025-06-06, 1404/03/16

Registrant information

Name
Sogol Asgari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8836 3185

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-23, 1404/05/01

Expected recruitment end date
2025-10-22, 1404/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Hyaluronic Acid injection with and without corticosteroids on the severity of pain and physical function in patients with knee Osteoarthritis grade 2 and 3

Public title
Comparison of Hyaluronic Acid injection with and without corticosteroids on the severity of pain and physical function in patients with knee Osteoarthritis grade 2 and 3 in Imam Hossein hospital

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with grade 2 and 3 knee osteoarthritis are candidates for therapeutic interventions for pain control and refer to the pain clinic of Imam Hossein Hospital.

Exclusion criteria:
Patients with bone malignancies People addicted to opioid History of allergy to hyaluronic acid or the corticosteroid class of drugs patient dissatisfaction

Age
From **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted Randomized Blocks :In this method, 10 random blocks are generated by computer Software R. Each block includes 5 people in the intervention group and 5 people in the control group. The order of these people is randomly arranged by computer and people are assigned to groups in the same way. At the end of each block, a new block of 10 is produced and this process will continue until the final sample volume is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
Forms with numbers 1 and 2 inside the packaged envelopes are used to group patients, which are given to patients randomly and the patients are not aware of the groupings. Before the injection begins, the envelope is opened by the anesthesiologist in charge of the patient and given to the patient based on the intervention or control group that was prepared in advance. The clinical caregiver, the evaluator and the results recorder, and the participant are not aware of the grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice for Research and Technology, Shahid Beheshti University of Medical Sciences

Street address
Velenjak, Yemen Street, Shahid Shahriari Square

City
TEHRAN

Province
Tehran

Postal code
1985717443

Approval date
2025-05-10, 1404/02/20

Ethics committee reference number
IR.SBMU.MSP.REC.1404.055

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M15.9

ICD-10 code description
Generalized osteoarthritis NOS

Primary outcomes

1

Description
Examining changes in bone pain intensity

Timepoint
The total follow-up period is six months in 4 sessions. At time zero (time of study entry and before drug injection), one month, three months, and 6 months after injection.

Method of measurement
VAS (Visual analog scale) pain rating tool

2

Description
Assessing the extent of improvement in physical performance

Timepoint
The total follow-up period is six months in 4 sessions. At time zero (time of study entry and before drug injection), one month, three months, and 6 months after injection

Method of measurement
Based on WOMAC criteria

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Injection of 40 mg of hyaluronic acid alone (cross-linked hyaluronic acid) in the knee joint from the brand Rodiyax-C
Category
Treatment - Drugs

2

Description
Intervention group: Injection of 44 mg of hyaluronic acid (cross-linked hyaluronic acid) and 9 mg of Triamcinolone Hexacetonide (corticosteroid) in the knee joint from the brand Rodiyax -T
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
mam Hussein Hospital
Full name of responsible person
sogol asgari
Street address
Makhsoos
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
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
Amirhoosain solaimaki
Position
Student
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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