Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparative study of the efficacy of piroxicam ampoule mesotherapy injection and shockwave modality on the clinical manifestations of knee osteoarthritis patients

Protocol summary

Study aim
Comparison of effectiveness of piroxicam ampoule mesotherapy injection and shockwave modality on clinical manifestations and performance in patients with knee arthritis

Design
The clinical trial has a control group, with parallel groups, a blind strain, randomized, phase two on 60 patients, the method of random assignment in This study is the permutation block method of 4

Settings and conduct
Project location: Imam Reza Physical Medicine and Rehabilitation Clinic the patients are divided into two groups, the first group is the mesotherapy injection of piroxicam ampoule in certain points of the knee and the second group is the shockwave modality in the painful points around the knee. Blinding is also done in a one-way blind way where the clinical supervisor does not know the type of study

Participants/Inclusion and exclusion criteria
Inclusion criteria: mild and moderate osteoarthritis of the knee exclusion criteria: history of knee injection and knee injury, any kind of surgery on the knee. Various diseases including diabetes and...

Intervention groups
The first group: patients received a subcutaneous injection containing a Combination of piroxicam and lidocaine 2%, at the acupuncture points ST34, ST35, SP9, BL 38, SP10, LR7 around the knee. After 10 days, the injection will Be done again (each patient will receive two mesotherapy sessions). The second group treated with shockwave modality, patients will receive 0.05 MJ/mm2 of total energy with 1000 pulses per week for 3 weeks.

Main outcome variables
Patient performance ,dependent ,somewhat continuous Pain level ,dependent ,somewhat discrete

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250622066221N1**
Registration date: **2025-08-18, 1404/05/27**
Registration timing: **prospective**

Last update: **2025-08-18, 1404/05/27**
Update count: **0**

Registration date
2025-08-18, 1404/05/27

Registrant information

Name
Ramin Ardeshiri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-02, 1404/06/11

Expected recruitment end date
2026-02-10, 1404/11/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the efficacy of piroxicam ampoule mesotherapy injection and shockwave modality on the clinical manifestations of knee osteoarthritis patients

Public title
A comparative study of the efficacy of piroxicam ampoule mesotherapy injection and shockwave modality on the clinical manifestations of knee osteoarthritis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Mild to moderate knee osteoarthritis

Exclusion criteria:
Injections in or around the knee joint in the last three months . Use of NSIAD in the last three days .History of cancer ,diabetes ,rheumatological disease and vascular collagen .Heat and redness in the knee ,History of knee injury ,History of knee Arthroplasty or other surgeries on the knee ,Presence of active Radiculopathy ,myopathy ,peripheral neuropathy ,Pregnancy or breastfeeding ,BMI>42 ,Allergy to piroxicam and other NSAID ,Severe gastrointestinal ,cardiovascular ,liver and kidney disease ,Any serious systemic or local infection such as brucellosis , Patients who have other musculoskeletal complications which Causes lower limb pain like secondary arthritis ,Patients who do Not complete the informed consent form to participate in the Study .

Age
From **35 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation method in this study will be the permuted block randomization with blocks of size four. In this method, "A" represents the individual receiving the intervention, and "B" represents the individual receiving the control. Considering blocks of four, the total number of possible permutations is six, which are: ABAB, BABA, AABB, BBAA, ABBA, and BAAB. Then, using a table of random numbers and assigning codes from 0 to 9 to each permutation, a random list of 60 assignments is generated. This list includes 25 blocks of four (4 × 25 = 60, which corresponds to the total sample size). The order of assigning each method to the study participants is then determined accordingly. For example, the permutations are assigned codes as follows: ABAB = 0, BABA = 1, AABB = 2, BBAA = 3, BAAB = 4, and ABBA = 5 to 9. Then, using a table of random numbers, a random starting point is selected, and 25 numbers are randomly chosen (either row-wise or column-wise). The permutation corresponding to each selected number is recorded. (The order of the permutations will be arranged from left to right.) This process determines the allocation of all 60 participants into the two groups, A and B.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study is one sided blind Clinical caregiver: to the person who is in charge of the care and follow-up of patients how to complete the questionnaires ,this person has no knowledge of the type of patients intervention .

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Emam hosaein dormitory hedaiat street

City
Shiraz

Province
Fars

Postal code
7134934748

Approval date
2025-08-17, 1404/05/26

Ethics committee reference number
IR.SUMS.MED.REC.1403.751

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Osteoarthritis of knee

Timepoint

Measurement of knee joint cartilage thickness and evaluation of knee effusion before immediately after and one month after injection of piroxicam ampoule and shockwave modality

Method of measurement

Visual analog scale , western Ontario and Mc master universities arthritis index , Oxford knee scale

Secondary outcomes

1

Description

Improve pain and function

Timepoint

Investigation of pain improvement and performance ten days and one month after piroxicam mesotherapy injection and shockwave modality

Method of measurement

Visual analog scale , Western Ontario and Mc Master universities arthritis index ,oxford knee scale

Intervention groups

1

Description

The first intervention group: Patients received subcutaneous injections containing a combination of 20 mg, 1 ml of piroxicam and 5 cc of lidocaine 2%, in acupuncture points ST34, ST35, SP9, BL 38, SP10, LR7 around the knee ,The angle of the needle when entering the skin should be 30-45 degrees, after 10 days, the injection will be done again (each Patient will receive two mesotherapy sessions).The second intervention group: Under treatment with shock wave modality, patients will receive 0.05 millijoules per square millimeter of total energy with 1000 pulses per week for 3 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam reza clinic

Full name of responsible person

Sharareh roshanzamir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Ramin Ardeshiri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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 further information

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