Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of efficacy of Erqonasa ointment in osteoarthritis of the knee joint: a randomized, double-blind, placebo-controlled trial: A Pilot Study

Protocol summary

Study aim
To evaluate the efficacy of Erqonasa topical ointment in reducing knee osteoarthritis pain compared with 1% diclofenac gel and placebo gel in a randomized clinical trial.

Design
This study is a randomized, double-blind, parallel-group clinical trial with random allocation into three groups, conducted on 75 patients.

Settings and conduct
Eligible participants will be recruited from patients attending Hazrat Rasoul Akram Hospital after obtaining informed consent and will be randomly assigned into three groups: intervention group 1 receiving Eroqonasa topical ointment, intervention group 2 receiving 1% diclofenac gel, and the control group receiving placebo gel; all groups will receive the usual treatment. The required sample size was estimated as 60; however, considering a 20% dropout rate, 75 participants will be enrolled. The study is designed as a double-blind trial, in which both patients and the investigator are unaware of group allocation.

Participants/Inclusion and exclusion criteria
Participants include patients with primary knee osteoarthritis aged above 40 years, with pain severity between 4 and 10 based on VAS score , a history of pain exacerbation after discontinuation of NSAIDs or acetaminophen, and written informed consent. Patients with secondary osteoarthritis, history of joint surgery or intra-articular injection in the past six months, severe systemic diseases, uncontrolled cardiovascular disease, liver or kidney disease, fibromyalgia or other disabling conditions, and pregnant or breastfeeding women are not included in the study.

Intervention groups
Intervention group 1 receives Erqonasa ointment every 8 hours, intervention group 2 receives 1% diclofenac gel every 8 hours, and the control group receives placebo gel every 8 hours; all three groups also receive the usual treatment.

Main outcome variables
Pain severity, Joint stiffness, Daily Function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260425069160N1**
Registration date: **2026-05-02, 1405/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-02, 1405/02/12**
Update count: **0**

Registration date
2026-05-02, 1405/02/12

Registrant information

Name
mahyar rezvani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-02, 1405/02/12

Expected recruitment end date
2027-05-02, 1406/02/12

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of Erqonasa ointment in osteoarthritis of the knee joint: a randomized, double-blind, placebo-controlled trial: A Pilot Study

Public title

Efficacy of Erqonasa ointment in osteoarthritis of the knee

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnose of primary osteoarthritis of knee Age above 40 years Pain exacerbation after discontinuation of NSAIDs or acetaminophen (at least two times) Written informed consent Pain severity based on VAS score between 4 and 10

Exclusion criteria:

Secondary Osteoarthritis Joint surgery or intra-articular injection in the past six months Joint replacement Severe systemic diseases (e.g., infection) Fibromyalgia or other disabling diseases Pregnancy and breastfeeding Uncontrolled cardiovascular disease Liver or kidney disease

Age

From **40 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization for 75 participants is performed using Random Allocation software with a stratified randomization method. Participants are first stratified into moderate and severe pain groups, and within each stratum, random allocation to three groups is performed using a block randomization method based on the software-generated list.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is conducted as a double-blind trial. Participants are randomly allocated into three groups using Random Allocation software. Allocation is based on coded groups (A, B, and C), and interventions are provided in identical labeled forms without revealing their content. Participants, treating physician, and outcome assessors are blinded to group allocation. Outcomes are recorded using participant codes, and blinding is maintained until completion of data collection.

Placebo

Used

Assignment

Parallel

Other design features

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,Tehran,Iran

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Province

Tehran

Postal code

1449614535

Approval date

2025-09-16, 1404/06/25

Ethics committee reference number

IR.IUMS.REC.1404.624

Health conditions studied

1

Description of health condition studied

Osteoarthritis of knee

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Pain severity measured by VAS scale

Timepoint

Before intervention and four weeks after the start of intervention

Method of measurement

Pain severity measured using the VAS scale by physician assessment

Secondary outcomes

1

Description
Joint stiffness by WOMAC
Timepoint
Before intervention, two weeks and four weeks after the start of intervention
Method of measurement
Joint stiffness measured using the WOMAC questionnaire by physician assessment

2

Description
Physical function by WOMAC
Timepoint
Before intervention, two weeks and four weeks after the start of intervention
Method of measurement
Physical function measured using the WOMAC questionnaire by physician assessment

3

Description
Pain severity by WOMAC
Timepoint
Before intervention, two weeks and four weeks after the start of intervention
Method of measurement
Pain severity measured using the WOMAC questionnaire by physician assessment

4

Description
comparison of oral acetaminophen consumption across three groups
Timepoint
The fourth weeks after the start of the study
Method of measurement
Oral acetaminophen consumption (mg/day) recorded based on patient self-report in data collection forms

Intervention groups

1

Description
Intervention group: The intervention group will receive Erqonasa topical ointment manufactured by Kurdistan Shafa Pharmaceutical Company (Zemade Mafasel) three times a day for 4 weeks, along with the usual treatment. If pain is intolerable despite interventions, oral acetaminophen up to 2 g per day is permitted, and its consumption is recorded.
Category
Treatment - Drugs

2

Description
Second Intervention group: The second Intervention group will receive Diclofenac 1% topical gel manufactured by Sobhan Pharmaceutical Company three times a day for 4 weeks, along with the usual treatment. If pain is intolerable despite interventions, oral acetaminophen up to 2 g per day is permitted, and its consumption is recorded.
Category
Treatment - Drugs

3

Description
Control group: The control group will receive topical Placebo gel three times a day for 4 weeks, along with the usual treatment. If pain is intolerable despite interventions, oral acetaminophen up to 2 g per day is permitted, and its consumption is recorded.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital of Hazrat Rasool Akram
Full name of responsible person
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Sponsors / Funding sources

1

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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
Personal

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

After publishing the related article in international journals

To whom data/document is available

Researchers in the field of medicine and pharmacy

Under which criteria data/document could be used

Development of science and expand evidence related to treatment in further research

From where data/document is obtainable

Parastoo Mirzabeygi pmirzabeygi@gmail.com

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

Using the journal email to communicate and register a request to use the study data

Comments