Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Formulation and Evaluation of a Topical Chamomile Preparation for Reducing Pain and Improving Function in Patients with Knee Osteoarthritis Compared with Diclofenac Gel: A Double-Blind Randomized Controlled Trial

Protocol summary

Study aim

Investigating the Effect of a Topical Chamomile Preparation on Pain Reduction and Functional Improvement in Patients with Knee Osteoarthritis Compared with Diclofenac Gel

Design

This study is a randomized, controlled, double-blind, parallel-group clinical trial involving 72 patients with primary knee osteoarthritis. Participants will be allocated at a 1:1 ratio to either the intervention group or the control group. Individual participants will be randomized using block randomization, and the allocation sequence will be generated using randomization software.

Settings and conduct

This study will be conducted as a randomized, controlled, double-blind, parallel-group clinical trial involving 72 patients with primary knee osteoarthritis at the clinics affiliated with Babol University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: include a clinical diagnosis of primary knee osteoarthritis, knee pain, radiographic evidence of osteophytes, age ≥50 years, morning knee stiffness lasting less than 30 minutes, knee crepitus during movement, Participants with grade 1 to 3 osteophyte severity based on the Kellgren–Lawrence classification on knee radiographs, and participants with a pain intensity score of ≥3 and ≤8 on the Visual Analog Scale. Exclusion criteria: include severe osteoarthritis, limited mobility, and the absence evidence of osteoarthritis.

Intervention groups

Participants in the intervention group will receive the topical chamomile preparation, while those in the control group will receive 1% diclofenac gel, with both treatments applied as one fingertip unit to the affected knee every 8 hours throughout the study period.

Main outcome variables

The study outcomes will include joint pain, joint stiffness, physical activity, quality of life, osteophyte severity, and treatment duration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211218053445N2**
Registration date: **2026-09-05, 1405/06/14**
Registration timing: **prospective**

Last update: **2026-09-05, 1405/06/14**
Update count: **0**

Registration date

2026-09-05, 1405/06/14

Registrant information

Name

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2026-11-22, 1405/09/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Formulation and Evaluation of a Topical Chamomile Preparation for Reducing Pain and Improving Function in Patients with Knee Osteoarthritis Compared with Diclofenac Gel: A Double-Blind Randomized Controlled Trial

Public title
Effect of Topical Chamomile on Pain and Function in Patients with Knee Osteoarthritis Compared with Diclofenac Gel
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Clinically confirmed primary knee osteoarthritis Knee pain Radiographic evidence of osteophytes Age of 50 years or older Morning joint stiffness lasting less than 30 minutes Crepitus during knee movement Participants with grade 1 to 3 osteophyte severity based on the Kellgren–Lawrence classification on knee radiographs. Participants with a pain intensity score of ≥3 and ≤8 on the Visual Analog Scale.
Exclusion criteria:
Severe osteoarthritis Patients with impaired mobility Absence of atherosclerosis
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, following confirmation of the inclusion and exclusion criteria and completion of the baseline assessment, participants will be assigned at a 1:1 ratio to one of two groups using block randomization: a group receiving a topical chamomile product and a group receiving diclofenac gel. Randomization will be performed at the individual level. Neither stratified nor quasi-randomization methods will be used. The randomization sequence will be generated using randomization software. To ensure allocation concealment, the sequence will be placed in sequentially numbered, opaque, sealed envelopes. The appropriate envelope will be opened only after completion of the baseline assessment and confirmation of the participant's eligibility and enrollment in the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted as a double-blind randomized controlled trial. Participants and outcome assessors will be blinded to group allocation. Participants will not be aware of the type of intervention they receive (topical chamomile preparation or diclofenac gel), and study outcomes, including pain and functional status, will be assessed by an individual who is unaware of participants' group assignments. The researcher responsible for outcome assessment and data collection will also remain blinded to group allocation. Group allocation will be performed after completion of the baseline assessment and confirmation of the participant's eligibility and enrollment. Allocation information will not be disclosed to those responsible for outcome assessment. If feasible, statistical analyses will also be performed using coded groups, with the analyst blinded to the identity of the intervention groups. All participants will provide written informed consent before enrollment after receiving a full explanation of the study objectives, procedures, potential benefits, and possible risks.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Babol University of Medical Sciences
Street address
Babol Ethics Committee, Babol University of Medical Sciences, Ganj-Afrooz Street.
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Province
Mazandaran
Postal code
4717647754
Approval date
2025-12-08, 1404/09/17
Ethics committee reference number
IR.MUBABOL.REC.1404.186

Health conditions studied

1

Description of health condition studied

Primary Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Change in knee pain intensity based on the Visual Analog Scale score

Timepoint

Measurement of knee pain intensity using the Visual Analog Scale at baseline, before initiation of the intervention, and at the end of each week during weeks 1 through 4 after initiation of the intervention.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Change in knee joint symptoms

Timepoint

At baseline, before initiation of the intervention, and at the end of weeks 1, 2, 3, and 4.

Method of measurement

KOOS Questionnaire

2

Description

Change in physical activity

Timepoint

At baseline, before initiation of the intervention, and at the end of weeks 1, 2, 3, and 4.

Method of measurement

KOOS Questionnaire

3

Description

Change in sport and recreational function

Timepoint

At baseline, before initiation of the intervention, and at the end of weeks 1, 2, 3, and 4.

Method of measurement

KOOS Questionnaire

4

Description

Change in quality of life

Timepoint

At baseline, before initiation of the intervention, and at the end of weeks 1, 2, 3, and 4.

Method of measurement

KOOS Questionnaire

Intervention groups

1

Description

Intervention group: Participants will apply the topical chamomile preparation at a dose of one fingertip unit to the affected knee every 8 hours throughout the study period. The topical chamomile preparation is formulated based on an aqueous extract of chamomile flowers and contains Carbomer 940 gel base, peppermint essential oil, propylene glycol, methylparaben, propylparaben, and triethanolamine. The preparation will be standardized based on apigenin content and subjected to microbiological quality control.

Category

Treatment - Drugs

2

Description

Control group: Participants will apply 1% diclofenac gel at a dose of one fingertip unit to the affected knee every 8 hours throughout the study period. The 1% diclofenac gel will be provided in a 60 geram tube and manufactured by Sobhan Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol University of Medical Sciences

Full name of responsible person

Mohammad Hossein Manian

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Sponsors / Funding sources

1

Sponsor

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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
Babol 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
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Position
Assistant professor

Latest degree
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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
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable