Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the therapeutic effect of formulation containing Boswellia sacra and Zingiber officinale and Apium graveolens seed and Curcuma longa in patients with Osteoarthritit

Protocol summary

Study aim

To evaluate the therapeutic effects of a formulation containing Boswellia sacra, Zingiber officinale, Apium graveolens seeds, and Curcuma longa rhizome in patients with knee osteoarthritis.

Design

Two arm, parallel group, double blind, placebo controlled, randomized clinical trial with 88 participants, 1:1 allocation, conducted at a single center.

Settings and conduct

The study will be conducted at Imam Reza Hospital in Kermanshah, Iran. Eligible patients with knee osteoarthritis will be randomly assigned to the intervention or placebo group and followed for 90 days. Participants, care providers, investigators, and outcome assessors will be blinded to treatment allocation. Identical intervention and placebo tablets will be used to maintain blinding.

Participants/Inclusion and exclusion criteria

Adults aged 18 to 80 years with knee osteoarthritis will be included. Participants must have radiographic evidence of knee osteoarthritis and be willing to provide informed consent. Individuals with conditions or medication use that may interfere with the study intervention or outcomes will be excluded.

Intervention groups

Participants will be randomly allocated to two groups. The intervention group will receive one tablet daily containing Boswellia oleo gum resin 225 mg, ginger extract 60 mg, celery seed extract 91 mg, and turmeric rhizome extract 80 mg for 90 days. The control group will receive one identical placebo tablet daily for 90 days.

Main outcome variables

The primary outcome is the change in the Western Ontario and McMaster Universities Osteoarthritis Index score from baseline to day 90. Secondary outcomes include changes in inflammatory and oxidative stress biomarkers, including interleukin 6, interleukin 1 beta, tumor necrosis factor alpha, glutathione peroxidase, superoxide dismutase, vascular endothelial growth factor, and matrix metalloproteinases.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260911071008N1**
Registration date: **2026-09-19, 1405/06/28**
Registration timing: **retrospective**

Last update: **2026-09-19, 1405/06/28**
Update count: **0**

Registration date

2026-09-19, 1405/06/28

Registrant information

Name

Mohammad Mehdi Gravandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-08-22, 1405/05/31

Actual recruitment start date

2025-12-22, 1404/10/01

Actual recruitment end date

2026-03-20, 1404/12/29

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of formulation containing Boswellia sacra and Zingiber officinale and Apium graveolens seed and Curcuma longa in patients with Osteoarthritit

Public title

Effect of a herbal formulation containing frankincense, ginger, celery seed, and turmeric on symptoms of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 80 years. Diagnosis of knee osteoarthritis. Radiographic evidence of knee osteoarthritis based on the Kellgren–Lawrence grading system. Ability and willingness to participate in the study and provide informed consent. Ability to complete the WOMAC questionnaire and comply with the study procedures and follow-up visits.

Exclusion criteria:

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **88**

Actual sample size reached: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated in a 1:1 ratio to either the intervention group or the placebo control group using a block randomization method with variable block sizes. The randomization sequence will be generated independently, and allocation will be concealed using sequentially numbered, opaque, sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, care providers, investigators, and outcome assessors will be blinded to the treatment allocation throughout the study. The intervention and placebo tablets will be identical in appearance, shape, color, size, and packaging, and will be coded using unique identification numbers that do not reveal the treatment assignment. The randomization code will be generated and securely maintained by an independent person who is not involved in participant recruitment, treatment administration, outcome assessment, or data analysis. Participants will receive the assigned tablets according to the randomization code, without being informed of their group allocation. Care providers and investigators involved in participant management will remain unaware of the treatment assignment. Outcome assessors will also be blinded to group allocation when collecting and assessing WOMAC scores and other study outcomes. Laboratory personnel involved in the assessment of biochemical and inflammatory biomarkers will be blinded to treatment allocation by using coded samples. The treatment allocation code will remain concealed until completion of the study and finalization of the primary analyses, except in the event of a medical emergency requiring unblinding.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Kermanshah, Shahid Beheshti Boulevard, Medical Sciences Building No. 2, Deputy of Research and Technology

City

kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2026-05-09, 1405/02/19

Ethics committee reference number

IR.KUMS.REC.1405.219

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis, a degenerative joint disease characterized by pain, stiffness, and impaired physical function.

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description
Change in the Western Ontario and McMaster Universities Osteoarthritis Index score from baseline to day 90.
Timepoint
Baseline and day 90 after initiation of the intervention.
Method of measurement
The primary outcome will be measured using the Western Ontario and McMaster Universities Osteoarthritis Index questionnaire, a validated patient reported outcome measure for assessing pain, stiffness, and physical function in patients with knee osteoarthritis. The questionnaire will be completed at baseline and on day 90.

Secondary outcomes

empty

Intervention groups

1

Description
InterventioIntervention group: Participants will receive one tablet daily for 90 days containing Boswellia oleo gum resin 225 mg, ginger extract 60 mg, celery seed extract 91 mg, and turmeric rhizome extract 80 mg.n group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital, Kermanshah, Iran
Full name of responsible person
Mohammad Hosein Farzaei
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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
Kermanshah 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
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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
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