Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effects of Boswellia serrata, Zingiber officinale and Elaeagnus angustifolia mixture on pain, physical activity, and joint stiffness in patients with knee osteoarthritis: A randomized, placebo-controlled clinical trial

Protocol summary

Study aim
Studying the effects of Boswellia serrata, Zingiber officinale and Elaeagnus angustifolia mixture on pain, physical activity, and joint stiffness in patients with knee osteoarthritis

Design
This clinical trial study will be conducted in a double-blind phase 2-3 on 60 patients with knee osteoarthritis. Patients are randomly divided into two parallel groups. After completing the relevant questionnaires, patients will be given a herbal medicine bottle containing 60 herbal medicine capsules or placebo and its code (A or B) will be recorded in the patient's medical records.

Settings and conduct
Patients with knee osteoarthritis referring to Baghiatallah Hospital according to inclusion criteria randomly divided to herbal medicine or placebo groups. Except main investigator, non of the medical stuff, patients, data collector and who evaluate the outcome, are unaware of the medication type.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male or female patients aged 40 to 80 years who have osteoarthritis of the knee 1 or 2 according to the criteria of the American College of Rheumatology. Exclusion criteria: Secondary osteoarthritis; arthroscopy; surgery; injection into the target knee joint within the past 6 months; any serious systemic disease or chronic inflammatory disease; blood clotting disorders; use of anticoagulants such as warfarin and heparin; use of antiplatelet drugs such as aspirin and thrombolytic drugs

Intervention groups
Herbal Medicine group: Patients take one capsule of 500 mg of herbal medicine orally every 12 hours after meals for 2 months. Placebo group: Patients take one capsule of 500 mg of placebo orally every 12 hours after meals for 2 months.

Main outcome variables
Joint pain using Visual Analog Scale questionnaire and joint stiffness and physical activity using Western Ontario and McMaster Universities Arthritis Index questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001157N23**
Registration date: **2025-11-15, 1404/08/24**
Registration timing: **prospective**

Last update: **2025-11-15, 1404/08/24**
Update count: **0**

Registration date
2025-11-15, 1404/08/24

Registrant information

Name
Hasan Fallah Huseini

Name of organization / entity
Institute of Medicinal Plants

Country
Iran (Islamic Republic of)

Phone
+98 26 3476 4010

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fallah@imp.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2025-11-21, 1404/08/30

Expected recruitment end date

2026-03-15, 1404/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effects of Boswellia serrata, Zingiber officinale and Elaeagnus angustifolia mixture on pain, physical activity, and joint stiffness in patients with knee osteoarthritis: A randomized, placebo-controlled clinical trial

Public title

Effects of Boswellia serrata, Zingiber officinale and Elaeagnus angustifolia mixture on pain, physical activity, and joint stiffness in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with osteoarthritis visit to Baqiyatallah Hospital in Tehran Male or female patients aged 40 to 80 years According to the criteria of the American College of Rheumatology, Knees osteoarthritis grade 1 or 2

Exclusion criteria:

Arthroscopy, Surgery, or Injection to the target knee joint within the past 6 months History of knee replacement Any serious systemic disease (such as secondary infections and cardiovascular, liver, and kidney diseases) Any other chronic inflammatory disease Any history of alcohol and drug abuse Fibromyalgia and other debilitating diseases affecting the knees Blood clotting disorders, and or use of anticoagulants such as warfarin and heparin Use of antiplatelet drugs such as aspirin, and thrombolytic drugs Pregnant women, women who are planning to have children, and women who are breastfeeding are not included in the plan.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the block randomization method will be used. By visiting the website www.sealedenvelope.com and selecting the 'Randomization' tab, the 'Make a list' option will be clicked. After specifying the number of intervention groups, the sample size, and the block size (which is set to 4 in this study), a randomized list containing specific patient codes will be generated and used for the randomization process. A randomly generated list will be used to create a series of sequentially numbered, sealed envelopes. Each envelope will be marked with a unique patient code, and inside will be a card indicating the assigned intervention group. Following the enrollment of each eligible patient, the envelope corresponding to the next sequential code will be opened by the researcher. The patient will then be assigned to their intervention group based on the card contained within the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Letters A or B are labeled on herbal medicine or placebo cans. Other specifications on the labels are completely identical. Physician, nurse, patient, data collector and those who evaluate the outcome, are unaware of the nature and meaning of the letters A or B on the labels. Only the main investigator knows the nature of the labels. Patients are aware that they are either in the drug or in the placebo groups, but they are not aware of the type of group they are in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of Baghiatallah Hospital

Street address

Baqiyatallah University of Medical Sciences, Molasadra Ave, Vanak square

City

Tehran

Province

Tehran

Postal code

1484958693

Approval date

2025-10-06, 1404/07/14

Ethics committee reference number

IR.BMSU.BAQ.REC.1404.104

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M19.9

ICD-10 code description

Osteoarthritis, unspecified site

Primary outcomes

1

Description

Joint pain

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

The Visual Analogue Scale Questionnaire

2

Description

Joint stiffness

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

The Western Ontario and McMaster Universities Arthritis Index Questionnaire

3

Description

Physical activity

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

The Western Ontario and McMaster Universities Arthritis Index Questionnaire

Secondary outcomes

1

Description

Dose of acetaminophen used

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

Daily recording of the acetaminophen dose used by the patient

2

Description

Blood urea nitrogen

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

The level of urea nitrogen in the blood is measured by an autoanalyzer in the laboratory

3

Description

Creatinine

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

The level of creatinine in the blood is measured by an autoanalyzer in the laboratory

4

Description

Aspartate aminotransferase

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

The level of aspartate aminotransferase in the blood is measured by an autoanalyzer in the laboratory

5

Description

Alanine aminotransferase

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

The level of alanine aminotransferase in the blood is measured by an autoanalyzer in the laboratory

6

Description

Blood cell count

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

Blood cell counts are measured in the laboratory using a cell counter.

7

Description

Severity of arthritis

Timepoint

Before intervention and end of intervention after 2 months

Method of measurement

The Western Ontario and McMaster Universities Arthritis Index Questionnaire

Intervention groups

1

Description

Intervention group: Patients will orally take one 500 mg

capsule of the herbal mixture (containing frankincense, ginger, and wild olive) produced by the Medicinal Plants Research Center of Jihad Daneshghani, every 12 hours after meals for a period of 2 months.

Category

Treatment - Drugs

2

Description

Control group: Patients will orally take one 500 mg capsule of the placebo (contains toasted flour) produced by the Medicinal Plants Research Center of Jihad Daneshghani, every 12 hours after meals for a period of 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bagheiat-allah Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Nasrin Qavami

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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

Iranian academic center for education culture and research

Proportion provided by this source

50

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

Iranian academic center for education culture and research

Full name of responsible person

Fallah Huseini Hasan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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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
No - There is not a plan to make this available