Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Study on the effects of Curcuma longa, Piper nigrum and Camellia sinensis extract mixture on the symptoms of knee osteoarthritis: a randomized controlled trial

Protocol summary

Study aim

Study on the effects of Curcuma longa, Piper nigrum and Camellia sinensis extract mixture on the symptoms of knee osteoarthritis: a randomized controlled trial

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: 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; Patients with Knees osteoarthritis grade 1 or 2. Exclusion criteria: Patients with history of 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) or any other chronic inflammatory disease; Any history of alcohol and drug abuse

Intervention groups

Intervention group: Patients will orally take one 500 mg capsule of the herbal mixture (containing Curcuma longa, Piper nigrum and Camellia sinensis) produced by the Medicinal Plants Research Center of Jihad Daneshghani, every 12 hours after meals for a period of 2 months. 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.

Main outcome variables

Joint pain using Visual Analog Scale questionnaire; 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: **IRCT20080901001157N24**
Registration date: **2026-05-09, 1405/02/19**
Registration timing: **prospective**

Last update: **2026-05-09, 1405/02/19**
Update count: **0**

Registration date

2026-05-09, 1405/02/19

Registrant information

Name
Hasan Fallah Huseini
Name of organization / entity
Institute of Medicinal Plants
Country
Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-05-21, 1405/02/31
Expected recruitment end date
2026-11-21, 1405/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study on the effects of Curcuma longa, Piper nigrum and Camellia sinensis extract mixture on the symptoms of knee osteoarthritis: a randomized controlled trial

Public title
Effects of Curcuma longa, Piper nigrum and Camellia sinensis mixture on the symptoms of 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 Patients with Knees osteoarthritis grade 1 or 2
Exclusion criteria:
Patients with history of 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) or any other chronic inflammatory disease Any history of alcohol and drug abuse Patients with fibromyalgia and other debilitating diseases affecting the knees Blood clotting disorders, and or use of anticoagulants such as warfarin and heparin Use of anti-platelet 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
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

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)
Triple 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
2026-02-01, 1404/11/12
Ethics committee reference number
IR.BMSU.BAQ.REC.1404.134

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
The Western Ontario and McMaster Universities Arthritis Index Questionnaire

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 (Curcuma longa, Piper nigrum and Camellia sinensis) 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
Reza Mohtashami
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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
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Research Complex of Jahad Daneshgahi, 55th km of Tehran-Qazvin Highway, Supa Boulevard, Kavosh Boulevard
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huseini_fallah@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
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Person responsible for scientific inquiries

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Bagheiat-allah University of Medical Sciences

Full name of responsible person
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Specialist
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Person responsible for updating data

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Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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