

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 staff, 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)

##### Phone

+98 26 3476 4010

##### Email address

fallah@imp.ac.ir

##### 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](http://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

#### Street address

Mollasadra Street, Vanak Square

#### City

Tehran

#### Province

Tehran

#### Postal code

1360136023

#### Phone

+98 21 2558

#### Email

reza\_mohtashami1979@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Iranian academic center for education culture and research

#### Full name of responsible person

Nasrin Qavami

#### Street address

Research Complex of Jihad Daneshgahi, 55th km of Tehran-Qazvin Highway, Supa Boulevard, Kavosh Boulevard

#### City

Karaj

#### Province

Alborz

#### Postal code

13601360

#### Phone

+98 26 3476 4010

#### Email

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

Medical Pharmacy

#### Street address

Institute of Medicinal Plants, ACECR Complex, Supa Boulevard, Poleh Kordan

#### City

Karaj

#### Province

Alborz

#### Postal code

3365166571

#### Phone

+98 26 3476 4010

#### Email

h.fallah@acecr.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Reza Mohtashami

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Bagheiat-allah University of Medical Sciences,  
Molasadra Ave., Vanak square

**City**

Tehran

**Province**

Tehran

**Postal code**

1484958693

**Phone**

+98 21 8806 8923

**Email**

reza\_mohtashami1979@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Iranian academic center for education culture and  
research

**Full name of responsible person**

Hasan Fallah Huseini

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Research Complex of Jihad Daneshgahi, Kavosh  
Boulevard, Supa Boulevard, 55-kilometer of the  
Tehran-Qazvin Highway

**City**

Karaj

**Province**

Alborz

**Postal code**

3365166571

**Phone**

+98 26 3476 4010

**Email**

huseini\_fallah@yahoo.com

**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