# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Study on the effects of Tanacetum Parthenium (feverfew) on the symptoms of knee osteoarthritis: A randomized controlled clinical trial

## Protocol summary

**Study aim**
Study of feverfew efficacy on knee osteoarthritis symptoms

**Design**
This double-blind, phase 3 randomized clinical trial is performed on 64 knee osteoarthritis patients divided equally into parallel drug and placebo groups. Drug and placebo with code A or B are prescribed to patients for 2 months. Random numbers table is used for randomization.

**Settings and conduct**
Eligible Patients are randomly divided into two groups and administered drug or placebo with the identification code A or B for 2 months. At the start and after 2 months, the blood tests complete blood count, serum glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase, creatinine, blood urea nitrogen, prothrombin time and partial thromboplastin time are performed. Also, at the start and after 1 and 2 months, Western Ontario and McMaster Universities Arthritis Index questionnaire is completed for the patients. Patients are monitored for occurrence of drug side effects for 2 months. After 2 months, the patients are requested to determine their satisfaction with the treatment on a 10 centimeter ruler.

**Participants/Inclusion and exclusion criteria**
Eligible patients are those with definite diagnosis of knee osteoarthritis based on radiological criteria, ages 40-80 years, the ability to take oral drug, willingness and ability to cooperate with study follow-ups. Exclusion criteria are secondary osteoarthritis, knee surgery or injection history , severe systemic diseases, coagulopathies, anticoagulant use, lactation, pregnancy, pregnancy planning, and allergy to Asteraceae plants.

**Intervention groups**
Drug group: Patients in this group take one 250 mg capsule of Tanacetum parthenium (feverfew) extract every 12 hours after meals for 2 months. Placebo group: Patients in this group take one 250 mg placebo capsule every 12 hours after meals for 2 months.

**Main outcome variables**
Total extent of knee osteoarthritis symptoms

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20090804002288N19**
Registration date: **2026-05-06, 1405/02/16**
Registration timing: **prospective**

Last update: **2026-05-06, 1405/02/16**
Update count: **0**

**Registration date**
2026-05-06, 1405/02/16

**Registrant information**

**Name**
Saeed Kianbakht

**Name of organization / entity**
Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-06-22, 1405/04/01

**Expected recruitment end date**
2026-10-23, 1405/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Study on the effects of Tanacetum Parthenium (feverfew) on the symptoms of knee osteoarthritis: A randomized controlled clinical trial

**Public title**

Effects of feverfew (Tanacetum Parthenium) on the knee osteoarthritis symptoms

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Diagnosis of knee osteoarthritis (grade 2 to 3 based on radiological criteria) Age between 40 and 80 years Ability of taking oral drugs and cooperation with treatment follow-up

**Exclusion criteria:**

Secondary osteoarthritis History of knee surgery or knee injection within the past 6 months Severe systemic diseases (cardiac, hepatic, renal, infectious) Coagulopathies or use of anticoagulant drugs Pregnancy, breastfeeding, or planning for pregnancy History of allergy to plants of the Asteraceae family (e.g., chicory, artichoke, daisy, sunflower)

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization method using random blocks and random numbers table are employed.The patients are randomly divided into two groups A and B. One group receives the drug and the other group receives placebo. Sealed envelopes are used for concealment of allocation of the patients to the groups A and B. The patients numbers are written on the outsides of the envelopes and allocations to the groups A or B are written on the insides of the envelopes. Each patient selects one envelope.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Bottles of drug and placebo are labeled with the code B or A. Other specifications on the labels are identical. Physician, nurse, patients, data collectors and those who evaluate the outcomes are unaware of the drug and placebo groups. Patients are aware that they are either in the drug or placebo group, 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**

Ethics Committee of Bagheiat-Allah University of medical sciences

**Street address**

Bagheiat-Allah University of medical sciences, Sheikh bahaee Street, Tehran. Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Approval date**

2026-02-02, 1404/11/13

**Ethics committee reference number**

IR.BMSU.BAQ.REC.1404.139

## Health conditions studied

### 1

**Description of health condition studied**

Primary knee osteoarthritis

**ICD-10 code**

M17.1

**ICD-10 code description**

Primary gonarthrosis

## Primary outcomes

### 1

**Description**

Total extent of knee osteoarthritis symptoms

**Timepoint**

At the start of study, and 1 and 2 months after intervention

**Method of measurement**

Western Ontario and McMaster Universities Osteoarthritis Arthritis Index questionnaire

## Secondary outcomes

### 1

**Description**
Degree of patients satisfaction
**Timepoint**
At the start of study and 2 months after intervention
**Method of measurement**
Ten centimeter ruler

### 2

**Description**
Serum glutamic oxaloacetic transaminase
**Timepoint**
At the start and 2 months after intervention
**Method of measurement**
Autoanalyzer

### 3

**Description**
Serum glutamic pyruvic transaminase
**Timepoint**
At the start and 2 months after intervention
**Method of measurement**
Autoanalyzer

### 4

**Description**
Blood creatinine
**Timepoint**
At the start and 2 months after intervention
**Method of measurement**
Autoanalyzer

### 5

**Description**
Blood Urea Nitrogen
**Timepoint**
At the start and 2 months after intervention
**Method of measurement**
Autoanalyzer

### 6

**Description**
Complete Blood Count
**Timepoint**
At the start and 2 months after intervention
**Method of measurement**
Autoanalyzer

### 7

**Description**
Prothrombin Time
**Timepoint**
At the start and 2 months after intervention
**Method of measurement**
Autoanalyzer

### 8

**Description**
Partial Thromboplastin Time
**Timepoint**
At the start and 2 months after intervention
**Method of measurement**
Autoanalyzer

### 9

**Description**
Drug side effects
**Timepoint**
During the study
**Method of measurement**
Patient report and blood tests

### 10

**Description**
Extent of knee joint pain
**Timepoint**
At the start and 1 and 2 months after intervention
**Method of measurement**
Western Ontario and McMaster Universities Arthritis Index questionnaire

### 11

**Description**
Extent of knee joint stiffness
**Timepoint**
At the start and 1 and 2 months after intervention
**Method of measurement**
Western Ontario and McMaster Universities Arthritis Index questionnaire

### 12

**Description**
Extent of patient physical function
**Timepoint**
At the start and 1 and 2 months after intervention
**Method of measurement**
Western Ontario and McMaster Universities Arthritis Index questionnaire

## Intervention groups

### 1

**Description**
Intervention group: Patients of this group consume one capsule containing 250 mg standardized hydro-alcoholic extract of Tanacetum Parthenium every 12 hours after meal for 2 months.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Patients of this group consume one placebo capsule containing 250 mg toasted powder every 12 hours after meal for 2 months.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Rheumatology clinic of Bagheiat-Allah Hospital
**Full name of responsible person**
Akram Rosamzadeh
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Bagheiat-allah University of Medical Sciences
**Full name of responsible person**
Abbasali Imani fuladi
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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**
Bagheiat-allah 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**
Bagheiat-allah University of Medical Sciences
**Full name of responsible person**
Akram Rostamzadeh
**Position**
Assistant of Rheumatology fellowship
**Latest degree**
Specialist
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Iranian academic center for education culture and research

**Full name of responsible person**
Saeed Kianbakht

**Position**
Assistant professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Pharmacology

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Institute of Medicinal Plants, Complex of Iranian Academic Center for Education, Culture and Research (ACECR), ACECR Ave., Exit of Baharestan Town, Karaj-Hashtgerd Highway

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skianbakht@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is 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

**Title and more details about the data/document**
All data after de-identification can be shared.

**When the data will become available and for how long**
Data are available one year after publication of the results for an infinite period of time.

**To whom data/document is available**
Data and documents will be available only for people working in academic institutions.

**Under which criteria data/document could be used**
No analysis on data or documents is permitted. Use of data and documents is permitted only with citation of the article in which they were published. The applicant for data or documents should mention the aim for access to data or documents.

**From where data/document is obtainable**
Application for data or documents should be sent to Dr. Akram Rostamzadeh with the email rostamzadehak@yahoo.com

**What processes are involved for a request to access data/document**
The applicant for data or documents should mention the reason and aim for the application. The application will be answered within at most 2 weeks.

**Comments**