Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Formulation and clinical evaluation (Phase 2 clinical trial) of complementary therapy with b-Caryophyllene in osteoarthritis patients: determination of effectiveness and safety

Protocol summary

Study aim
Clinical evaluation of b-Caryophyllene in osteoarthritis patients

Design
A double-blind, randomized, placebo-controlled, Phase 2 clinical trial study will be performed on 120 individuals divided into three groups.

Settings and conduct
The study will be performed on patients referred to the clinics of Mashhad University of Medical Sciences. After obtaining informed consent, patients are randomly divided into interventions 1 and 2 and placebo groups and take the drug daily for 8 weeks. Patients are evaluated weekly by a rheumatologist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Lack of proper response (VAS>30at the beginning of the study) to the analgesic drug meloxicam after at least two weeks of drug administration before the start of the study, Age between 40-70 years old, Patients with BMI lower than 37 Exclusion criteria: Patient's dissatisfaction with continued cooperation during the study, Need to perform any new therapeutic interventions during the study period, Active liver or kidney disease and malignancies, Secondary osteoarthritis, Patients treated with hormonal medicines, Patients treated with anticoagulants, Patients with a history of ischemic or hemorrhagic stroke, Patients with a history of deep vein thrombosis, Treatment with oral corticosteroids 4 weeks before the start of the study, Intra-articular injection of hyaluronic acid three months before the start of the study, Pregnancy, Patients who have had intra-articular corticosteroid injections in the last 4 weeks

Intervention groups
Intervention 1: Cap 30 mg of b-caryophyllene/day
Intervention 2: Cap 150 mg of b-caryophyllene/day
Control group (placebo): Cap containing corn oil base/day

Main outcome variables
Clinical indicators of knee osteoarthritis including pain, knee stiffness and physical function based on the WOMAC standardized questionnaire

General information

Reason for update
Due to material import problems, the patient collection has not yet started. However, the researchers predict that patient recruitment will begin on 20/02/2026.

Acronym
BCPOAMP

IRCT registration information
IRCT registration number: **IRCT20180103038199N9**
Registration date: **2021-12-05, 1400/09/14**
Registration timing: **prospective**

Last update: **2026-02-01, 1404/11/12**
Update count: **2**

Registration date
2021-12-05, 1400/09/14

Registrant information

Name
Vahid Reza Askari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3800 2264
Email address
askariv941@mums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01
Expected recruitment end date
2028-11-21, 1407/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Formulation and clinical evaluation (Phase 2 clinical trial) of complementary therapy with b-Caryophyllene in osteoarthritis patients: determination of effectiveness and safety

Public title
Evaluation of b-Caryophyllene in osteoarthritis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Lack of proper response (having a score higher than 30 on the VAS numerical-visual scale at the beginning of the study) to the analgesic drug meloxicam after at least two weeks of drug administration before the start of the study Age between 40-70 years old Patients with BMI lower than 37
Exclusion criteria:
Patient's dissatisfaction with continued cooperation during the study Need to perform any new therapeutic interventions during the study period Active liver or kidney disease and malignancies Secondary or suspected osteoarthritis Patients treated with hormonal medicines Patients treated with anticoagulants Patients with a history of ischemic or hemorrhagic stroke Patients with a history of deep vein thrombosis Treatment with oral corticosteroids 4 weeks before the start of the study Intra-articular injection of hyaluronic acid three months before the start of the study Pregnancy Patients who have had intra-articular corticosteroid injections in the last 4 weeks
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done by block method, the size of blocks is equal to six with three members A and B and C in a ratio of 1:1:1. Based on the sample size, 20 blocks are numbered in a different order from 1 to 20 and a random sequence of 20 blocks is determined using the site "WWW.Randomization.com", then the sequence of treatment groups A and B and C are determined in envelopes with number 1 Up to 120, with the inclusion of each eligible person, the envelope corresponding to the person's number is opened and the treatment group is determined.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the use of a placebo similar to the intervention treatment, the physician who associated with the participants and participants will not be informed of the assigned treatment. Also, the analyst will be unaware of the treatment assigned to the three groups. Finally, after analyzing the data, the researcher who prepared the packages reveals codes A, B, and C. The placebo will be very similar in treatment in terms of shape, consistency, packaging, and smell.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyzeh Cinema, University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2021-11-06, 1400/08/15
Ethics committee reference number
IR.MUMS.REC.1400.240

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee
ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Clinical indicators of osteoarthritis
Timepoint
At the beginning of the study and every week until the eighth week
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) standardized questionnaire

Secondary outcomes

1

Description
Complete Blood Cell Count with Differential
Timepoint
At the beginning and the end of the study
Method of measurement
Using an auto-analyzer system

2

Description
Interleukin-4 level
Timepoint
At the end of the study
Method of measurement
Using a laboratory kit

3

Description
Interferon-gamma level
Timepoint
At the end of the study
Method of measurement
Using a laboratory kit

4

Description
Interleukin-10 level
Timepoint
At the end of the study
Method of measurement
Using a laboratory kit

5

Description
high-sensitivity C-reactive protein (hs-CRP) level
Timepoint
At the beginning and the end of the study
Method of measurement
Using a laboratory kit

Intervention groups

1

Description
Intervention group: Patients with primary osteoarthritis receive a 30 mg soft capsule of b-caryophyllene made by Mashhad University of Medical Sciences. Patients take this soft capsule orally once a day for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Patients with primary osteoarthritis receive a 150 mg soft capsule of b-caryophyllene made by Mashhad University of Medical Sciences. Patients take this soft capsule orally once a day for 8 weeks.
Category
Treatment - Drugs

3

Description
Control group: Primary osteoarthritis patients receive a placebo soft capsule made by Mashhad University of Medical Sciences. Patients take this soft capsule orally once a day for 8 weeks. The placebo capsule is as same as intervention groups in terms of shape, colour, smell and taste. In order not to see the colour of the drug and placebo, the colour of the capsule is considered opaque and dark. The drugs are placed in blisters of the same shape, size, and colour.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics affiliated to Mashhad University of Medical Sciences
Full name of responsible person
Dr Vahid Reza Askari
Street address
Mashhad University of Medical Science, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2000
Email
askariv@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Majid Ghayour Mobarhan
Street address
Deputy of Research and Technology of the University , Qurashi Building, Next to Hoveyzeh Cinema, University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Email
ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Vahid Reza Askari
Position
Assistant professor of clinical pharmacology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of medicine, Paradise of University, Vakil-Abad Blvd., Azadi Sq., Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2264
Fax
Email
askariv@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Vahid Reza Askari
Position
Assistant professor of clinical pharmacology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of medicine, Paradise of University, Vakil-Abad Blvd., Azadi Sq., Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2264
Fax
Email
askariv@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Vahid Reza Askari
Position
Assistant professor of clinical pharmacology
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of medicine, Paradise of University, Vakil-Abad Blvd., Azadi Sq., Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2264
Fax

Email
askariv1@mums.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available