

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>30 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 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

AgeFrom **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 sizeTarget 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 Hoveyze 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

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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

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Deputy of Research and Technology of the University
, Qurashi Building, Next to Hoveyzeh Cinema,
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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

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Reza Askari

Position

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Person responsible for updating data

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Reza Askari

Position

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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

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