# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

26 Jul 2026

## Clinical trial of Portulaca oleracea extract capsule on clinical indicators of osteoarthritis

### Protocol summary

**Study aim**

The aim of this study is evaluated the effect of Portulaca oleracea extract capsule on clinical criteria of knee osteoarthritis.

**Design**

Randomized double-blind, controlled clinical trial, parallel, phase 2-3 on 80 patients with moderate knee osteoarthritis (40 patients in each group) using computer randomization method.

**Settings and conduct**

A total of 80 patients, based on diagnostic criteria College of Rheumatology American and opinion specialty respectable knee, knee osteoarthritis diagnosed and other inclusion criteria are eligible. After learning about the research and consent, refer to the management team and then for each questionnaire, including demographic data, comorbidities, medications consumer, medical history and its complications will be completed. Then patients randomly into two groups A and B. using the parcel divided Group A Portulaca oleracea capsule three times a day, and Group B placebo capsule three times a day will use. Both common treatment involves taking pills of meloxicom before and during the study will receive. The study will be done in Mashhad University of Medical Sciences.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria for this study include the following: Initial symptomatic osteoarthritis in at least one knee ; a score higher than 30 at baseline VAS scale; Obtain routine medical treatment (meloxicam tablets) for at least two weeks before the study; Exclusion criteria are as follows: The treatment with corticosteroids, hormonal drugs or hyaluronic acid before the start of the study

**Intervention groups**

Intervention Group: Portulaca oleracea capsule three times a day, and routine treatment with meloxicam tablets Control group: Placebo capsule three times a day, and routine treatment with meloxicam tablets

**Main outcome variables**

Improvement of clinical symptoms of osteoarthritis (pain, Joint stiffness and physical performance)

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20190406043175N5**
Registration date: **2021-08-30, 1400/06/08**
Registration timing: **prospective**

Last update: **2021-08-30, 1400/06/08**
Update count: **0**

**Registration date**

2021-08-30, 1400/06/08

**Registrant information**

**Name**

fatemeh forouzanfar

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3761 7318

**Email address**

forouzanfarf@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-10-23, 1400/08/01

**Expected recruitment end date**

2023-10-23, 1402/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Clinical trial of Portulaca oleracea extract capsule on clinical indicators of osteoarthritis

**Public title**
The effect of Portulaca oleracea capsule on knee osteoarthritis

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Initial symptomatic osteoarthritis in at least one knee by clinical or radiological criteria ACR (American College of Rheumatology) is approved Lack of proper adherence to routine drug treatment (meloxicam tablets) for at least two weeks before the study Score higher than 30 at baseline VAS scale

**Exclusion criteria:**
The intra-articular injection of hyaluronic acid in the three months before the start of the study The 4-week treatment with oral corticosteroids before the start of the study Patients with a history of deep vein thrombosis Active liver or renal disease and malignancies Secondary osteoarthritis or suspected Patients treated with hormonal drugs Patients treated with anticoagulation drugs Patients with a history of ischemic or hemorrhagic stroke

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

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In this study, we used Random Allocation software for randomization. The random sequence of samples was performed equally as Intervention and control groups using this software. For allocation concealment, sealed envelopes were used. In this method, each of the random sequences written on a card and is placed in the envelopes, respectively. Finally, the lid of the envelopes is glued and placed in a box, respectively. At the registration time, based on the order in which eligible participants enter the study, one of the envelopes of their choice will be opened and their assigned group will be revealed.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The capsules were packaged in the same shape and coded by an expert one in the research center using Random Allocation Software. Patients, and evaluators assess the outcome, are not aware of the contents of the package and grouping, and samples were delivered to patients randomly using Allocation concealment.

**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**
Mashhad University of Medical Sciences, Azadi Square, Mashhad

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
9177948564

**Approval date**
2021-04-13, 1400/01/24

**Ethics committee reference number**
IR.MUMS.MEDICAL.REC.1400.230

## Health conditions studied

### 1

**Description of health condition studied**
Knee osteoarthritis

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Pain

**Timepoint**
Early intervention, four weeks after the intervention, eight weeks after intervention

**Method of measurement**
Western Ontario and McMasters Universities Osteoarthritis Index (Womac) questionnaire and Visual Analog Scale (VAS) scale

### 2

**Description**

Joint stiffness

**Timepoint**

Early intervention, four weeks after the intervention, eight weeks after intervention

**Method of measurement**

(Womac) questionnaire and (VAS) scale

### 3

**Description**

Physical performance

**Timepoint**

Early intervention, four weeks after the intervention, eight weeks after intervention

**Method of measurement**

(Womac) questionnaire and (VAS) scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Portulaca oleracea capsule (prepared in Pharmacological Research Center of Medicinal Plants) three times a day, and routine treatment with meloxicam tablets.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Placebo capsule (prepared in Pharmacological Research Center of Medicinal Plants) three times a day, and routine treatment with meloxicam tablets.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Clinics affiliated to Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Forouzanfar

**Street address**

Mashhad University of Medical Science, Azadi Square

**City**

Mashad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3800 2000

**Email**

forouzanfarf@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Taphaghodi, Mohsen

**Street address**

Deputy of Research and Technology, Ghorashi Building, next to Hoveyzeh Cinema, University Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 1538

**Email**

tafaghodim@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**

Fatemeh Forouzanfar

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmacology

**Street address**

Mashhad University of Medical Sciences, Azadi square

**City**

Mashhad

**Province**
Razavi Khorasan
**Postal code**
9177948564
**Phone**
+98 51 3800 2538
**Email**
forouzanfarf@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Fatemeh Forouzanfar
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Pharmacology
**Street address**
Mashhad University of Medical Sciences, Azadi square
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9177948564
**Phone**
+98 51 3800 2538
**Email**
forouzanfarf@mums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Fatemeh Forouzanfar
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Pharmacology
**Street address**
Mashhad University of Medical Sciences, Azadi square
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9177948564
**Phone**
+98 51 3800 2538
**Email**
forouzanfarf@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