# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Effects of artichoke leaf extract supplementation on oxidative stress status, inflammatory markers and clinical symptoms in patients with knee osteoarthritis

## Protocol summary

**Study aim**

This study aimed to investigate the effect of artichoke leaf extract supplementation on oxidative stress status, inflammatory markers and clinical symptoms in patients with knee osteoarthritis

**Design**

This study is a two-arm parallel group randomized trial, conducted on 46 patients with knee osteoarthritis.

**Settings and conduct**

This randomized double blind placebo controlled trial will be performed in Zabol city. Participants will be randomly allocated to intervention and control groups.Participants and the principal investigator will be blinded to the study groups.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Willingness and ability to collaborate on project, aged 40-70 years from both sex, confirmation of bilateral primary knee osteoarthritis, body mass index between 25-35 kg/m2, Consumption of glucoseamine, chondrotin sulphate supplements and acetaminophene as anti-pain drug Exclusion criteria: Alcohol consumption; smoking; pregnant and lactating women; having an active synovitis; affected by cardiovascular disease, renal failure, diabetes mellitus, liver dysfunction, cancer; consumption of Furosemide, Probenecid, Sulphonamides, Methotrexate; Consumption of fish oil supplement or other antioxidant supplements currently or within 3 months before intervention; history of allergy to artichoke family plants and their products

**Intervention groups**

Subjects in the intervention group will receive four pills of artichoke leaf extract (each containing 450 mg, totaling 1800 mg daily), and placebo group will receive four placebo pills (containing corn flour) for 12 weeks.

**Main outcome variables**

Main outcome variables: Clinical symptoms including pain, joint stiffness and disability; Inflammatory markers including interleukin 1β (IL-1β), IL-6, and TNF-α; Oxidative markers including malondialdehyde (MDA), total antioxidant capacity (TAC), and total oxidant capacity (TOS).

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20250515065755N1**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **prospective**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

**Registration date**

2025-05-29, 1404/03/08

**Registrant information**

**Name**

Farshad Amirkhizi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 54 3223 2107

**Email address**

amirkhizi@zbmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-07-23, 1404/05/01

**Expected recruitment end date**

2026-07-23, 1405/05/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of artichoke leaf extract supplementation on oxidative stress status, inflammatory markers and clinical symptoms in patients with knee osteoarthritis

**Public title**

Effects of artichoke leaf extract in knee osteoarthritis

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Willingness and ability to collaborate on project aged 40-70 years from both sex Confirmation of bilateral primary knee osteoarthritis Body mass index between 25-35 kg/m2 Consumption of glucoseamine, chondroitin sulfate supplements and acetaminophen as anti-pain drug

**Exclusion criteria:**

Alcohol consumption Smoking Pregnant and lactating women Secondary osteoarthritis Having an active synovitis Having a history of knee injection within 6 months before intervention Neurological disorder that affects movement, muscle control and balance Affected by cardiovascular disease, renal failure, diabetes mellitus, liver dysfunction, cancer; affected by infectious or inflammatory disease or recent surgery Consumption of Furosemide, Probenecid, Anticoagulants, Anticonvulsant drugs, Sulphonamides, Methotrexate, Lithium salts and muscle relaxants currently or within 3 months before intervention Consumption of fish oil supplement or other antioxidant supplements currently or within 3 months before intervention History of allergy to artichoke family plants and their products

**Age**

From **40 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The participants will be randomly assigned to study groups using a block randomization procedure of size 4 and will be stratified by sex, age, and BMI. The Random Allocation Software (RAS) will be used by the study statistician to generate a random sequence.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, both participants and the principal investigator will be blinded to the study groups. To ensure that researchers and participants remain unaware of the type of supplement being administered, both the supplement and placebo will be placed in identical containers labeled with the appropriate code by an individual who is not the investigator, following a predetermined coding system.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Zabol University of Medical Sciences

**Street address**

Shahid Bagheri Ave, Shahid Rajaei St

**City**

Zabol

**Province**

Sistan-va-Balouchestan

**Postal code**

9861615881

**Approval date**

2025-03-04, 1403/12/14

**Ethics committee reference number**

IR.ZBMU.REC.1403.152

## Health conditions studied

### 1

**Description of health condition studied**

Knee osteoarthritis

**ICD-10 code**

M17

**ICD-10 code description**

Osteoarthritis of knee

## Primary outcomes

### 1

**Description**

Pain

**Timepoint**

Baseline and 12 weeks after intervention

**Method of measurement**

WOMAC questionnaire

**2**

**Description**
Joint stiffness
**Timepoint**
Baseline and 12 weeks after intervention
**Method of measurement**
WOMAC questionnaire

**3**

**Description**
Disability
**Timepoint**
Baseline and 12 weeks after intervention
**Method of measurement**
WOMAC questionnaire

**4**

**Description**
Oxidative markers
**Timepoint**
Baseline and 12 weeks after intervention
**Method of measurement**
Total antioxidant capacity (TAC) by using spectrophotometry, MDA by using thiobarbituric acid, Total oxidant capacity by using ELISA kit

**5**

**Description**
Inflammatory markers
**Timepoint**
Baseline and 12 weeks after intervention
**Method of measurement**
Serum levels of TNF-α, IL-1β and IL-6 by using ELISA kits

## Secondary outcomes

**1**

**Description**
Anthropometric measurements
**Timepoint**
Baseline and 12 weeks after intervention
**Method of measurement**
Weight and Height by using Seca scale and stadiometer respectively, waist circumference by using tape measure, Body mass index (BMI) will be calculated as weight in kilograms divided by the square of height in meters

**2**

**Description**
Energy and macro-nutrients intake
**Timepoint**
Baseline and 12 weeks after intervention
**Method of measurement**
3-day 24 hours food recall

## Intervention groups

**1**

**Description**
Intervention group: 1800 mg artichoke leaf extract as 4 tablets per day for 12 weeks
**Category**
Treatment - Other

**2**

**Description**
Control group: 1800 mg placebo containing corn starch as 4 tablets per day for 12 weeks
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Amir Al-Momenin Hospital
**Full name of responsible person**
Farshad Amirkhizi
**Street address**
Kilometer 3 Zabol Road - Zahedan
**City**
Zabol
**Province**
Sistan-va-Balouchestan
**Postal code**
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**Phone**
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**Email**
amirkhizi@zbmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Zabol University of Medical Sciences
**Full name of responsible person**
Bahman Fouladi
**Street address**
Shahid Rajaee Ave., Shahid Rajaee St.
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**Phone**
+98 54 3223 0768
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fouladi@zbmu.ac.ir
**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Zabol 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**
Zabol University of Medical Sciences

**Full name of responsible person**
Farshad Amirkhizi

**Position**
Associate professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nutrition

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
There is no further information.

**Study Protocol**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
No - There is not 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