# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

# The effect of oral administration and topical application of Linum usitatissimum L. (flax seed) oil along with a calorie restricted diet on anthropometric indices, pain, physical function, and serum indices of oxidative stress in patients with knee osteoarthritis

## Protocol summary

**Study aim**

The effect of oral administration and topical application of flax seed oil along with a calorie restricted diet on pain, physical function, and serum indices of oxidative stress in patients with knee osteoarthritis

**Design**

A parallel-group, double-blind, randomized, phase 3 clinical trial on 88 patients. Random array subset selection (RASS) was used for randomization.

**Settings and conduct**

Educational-therapeutic center of Imam Reza and Shohada of Tabriz After taking the blood samples of the patients and randomly assigning them to one of the groups, the supplements are delivered to the people for use for two weeks. After completion of the intervention period, the patients will visit Imam Reza Hospital and 5 cc of venous blood sample will be taken from them. To double-blind the conduct of the research, this will be done by an independent person from the study with using opaque sealed envelopes numbered 1, 2, 3, and 4 to conceal the allocation process. Subjects, clinical investigators, and the person responsible for statistical analysis will be blinded to the random assignment of subjects until the end of the study.

**Participants/Inclusion and exclusion criteria**

Adult men and women (over 40 years old)

**Intervention groups**

The first group receives flax seed oil in addition to topical flax seed oil along with a low calorie diet. The second group received a placebo of flax seed oil and topical flax seed oil along with a low calorie diet. The third group received flax seed oil plus topical paraffin oil as a placebo along with a low calorie diet. The fourth group received placebo flax seed oil and paraffin topical oil as a placebo along with a low calorie diet.

**Main outcome variables**

Changes in the average physical performance of the subjects based on the total score of the WOMAC index

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20161022030424N10**
Registration date: **2023-12-29, 1402/10/08**
Registration timing: **prospective**

Last update: **2023-12-29, 1402/10/08**
Update count: **0**

**Registration date**

2023-12-29, 1402/10/08

**Registrant information**

**Name**

Neda Dolatkhah

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-04-18, 1403/01/30

**Expected recruitment end date**

2024-09-20, 1403/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of oral administration and topical application of Linum usitatissimum L. (flax seed) oil along with a calorie restricted diet on anthropometric indices, pain, physical function, and serum indices of oxidative stress in patients with knee osteoarthritis

**Public title**

The effect of Linum usitatissimum L. (flax seed) oil along with a calorie restricted diet in patients with knee osteoarthritis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Diagnosis of knee osteoarthritis by a physical medicine specialist (mild, moderate) based on the diagnostic criteria of the American College of Rheumatology and the radiological evaluation of knee osteoarthritis by Clairgen Lawrence Overweight and obese people based on body mass index of 25-40 weight per square meter Not taking anticoagulants Absence of knee joint replacement surgery Absence of fractures involving the surface of the knee joint Absence of skin diseases in the knee area Absence of other systemic rheumatic diseases or RA, neuropathy, sensory disturbances due to drug, sedative or tobacco use

**Exclusion criteria:**

Treatment with oral or intra articular corticosteroids in the past 3 months

**Age**

From **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **88**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A block randomization method will be used to allocate participants to the groups with a 1:1:1:1 allocation using random allocation software (RAS) with block sizes of 4 and 8. Similarly sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Flaxseed and placebo food supplements are prepared and presented by Barij Essan Pharmaceutical Company, Kashan, Iran, and there will be no difference in color, shape, or taste between them. Liquid paraffin is packaged in containers similar to Flaxseed oil containers. Blocking and random allocation of the investigated subjects is done by a statistician outside the research team of the project. Outcome assessors, the person responsible for statistical analysis of the data, and the respondents will be blinded to the type of supplement received until the end of the study.

**Placebo**

Used

**Assignment**

Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research ethics committee of Tabriz University of Medical Sciences

**Street address**

Emam Reza hospital, Golgasht str., Azadi ave., Tabriz

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East Azarbaijan

**Postal code**

5165665931

**Approval date**

2023-09-25, 1402/07/03

**Ethics committee reference number**

IR.TBZMED.REC.1402.479

## 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**

Physical performance

**Timepoint**

Evaluation of physical performance at baseline (before

intervention) and 8 weeks after starting the oral and topical supplement of flaxseed oil.

**Method of measurement**

Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

## Secondary outcomes

### 1

**Description**

Pain intensity

**Timepoint**

Measurement of the pain intensity at baseline (before intervention) and 8 weeks after oral and topical supplement of flaxseed oil.

**Method of measurement**

Visual Analogue Scale

### 2

**Description**

Anthropometric indices

**Timepoint**

Measurement of the anthropometric indices at baseline (before intervention) and 8 weeks after oral and topical supplement of flaxseed oil.

**Method of measurement**

Seca digital scale

### 3

**Description**

Serum concentration of oxidative stress indices (MDA and TAC)

**Timepoint**

Measurement of the serum levels of inflammatory markers at baseline (before intervention) and 8 weeks after oral and topical supplement of flaxseed oil.

**Method of measurement**

Biochemical analysis

## Intervention groups

### 1

**Description**

The first intervention group: was given one flax seed oil (Barij Essential Oil Company, Kashan, Iran) three times a day for 8 weeks, plus topical flax seed oil (Barij Essential Oil Company, Kashan, Iran) 20 drops every 8 hours to rub on the knees along with a low-calorie diet.

**Category**

Treatment - Drugs

### 2

**Description**

The second intervention group: for 8 weeks, they received a placebo of flaxseed oil and topical flaxseed oil (Barij Essan Pharmaceutical Company, Kashan, Iran) three times a day, 20 drops every 8 hours to rub on the knees along with a low-calorie diet.

**Category**

Treatment - Drugs

### 3

**Description**

The third intervention group: For 8 weeks, they will receive one flaxseed oil three times a day (Barij Essence Pharmaceutical Company, Kashan, Iran) plus topical paraffin oil as a placebo to rub on the knees along with a low-calorie diet.

**Category**

Treatment - Drugs

### 4

**Description**

Control group: for 8 weeks, they received a placebo of flaxseed oil and topical paraffin oil as a placebo to rub on the knees three times a day along with a low-calorie diet.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Neda Dolatkhah

**Full name of responsible person**

Neda Dolatkhah

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

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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**
Tabriz 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**

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## Person responsible for updating data

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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

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