Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 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)

Phone

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Email address

dolatkhahn@tbzmed.ac.ir

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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Province

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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Full name of responsible person

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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

Name of organization / entity
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Position
Assistant Professor
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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