# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Efficacy of "Linum usitatissimum" Seed topical oil, on Clinical Sign of Knee Osteoarthritis Compared with Placebo, A Double Blind Clinical Trial

## Protocol summary


**Summary**

The aim of this study is to evaluate the therapeutic efficacy of traditional medicine product "Linum usitatissimum" seed oil in patients with knee osteoarthritis. First, patients with osteoarthritis of the knee, according to the inclusion criteria approved by orthopedic specialist are recruited. Then the patients are informed about the project and presence of case and control groups and after obtaining the consent; they will be enrolled into the project. Then patients allocated randomly with random block into the two treatment and placebo groups then they receive encoded drug (drug or placebo) and consume it according to the instructions. Patient and physician have no information about the drop content (double-blind randomized clinical trial). After filling the form and questionnaire by the patient, X-rays of the knee is requested (if there is no x-ray in the past 6 months) along with the necessary tests to find patients with severe kidney or liver problems for exclusion criteria, such as CBC, BUN, Cr, AST, ALT. During this period, patients can use up to 3 Tablet of Diclofenac 50mg per day. The "Linum usitatissimum" seed oil will be used topically for a period of 6 weeks every 8 hour with the dosage of 20 drops without massage.The placebo group will receive paraffin oil with same fashion. Patients will be visited at weeks 0, 3 and 6 and fill in the questionnaire at weeks 0, 6.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016020726407N1**
Registration date: **2016-09-15, 1395/06/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-09-15, 1395/06/25


**Registrant information**

**Name**
Nematollah Masoudi
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 8877 3521
**Email address**
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**Recruitment status**

**Recruitment complete**


**Funding source**

Traditional Medicine and Materia Medica Research Center (TMRC), Shahid Beheshti University of Medical Sciences (Tehran - Iran)


**Expected recruitment start date**

2016-07-20, 1395/04/30

**Expected recruitment end date**

2016-10-22, 1395/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy of "Linum usitatissimum" Seed topical oil, on Clinical Sign of Knee Osteoarthritis Compared with Placebo, A Double Blind Clinical Trial

**Public title**

Effect of flaxseed oil on clinical sign of Knee Arthrosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Patient between 40 to 70 yaers age with BMI less than 35 that fill clinical and radiologic criteria of ACR and have Kellgren-Lawrence Grading Scale III / II / I, with VAS over than 4 cm; Clinical and radiological criteria of ACR include: knee pain, osteophyte in radiography, plus at least 1 of 3 below criteria: age more than 50 years old; morning stiffness less than 30 minutes; crepitation of knee. Exclusion criteria: Acute arthritis, osteoarthritis due to rheumatologic disease such as RA and gout, infective arthritis, metabolic arthritis, traumatic, uncontrolled diabetes, known case of cardiac or hepatic disease, cancer; History of knee replacement surgery; Fibromyalgia, radiculopathy and neuropathy; Those who are unable to tolerate and complete the study or treatment and follow-up; As well as those who use more than 3 tablets Diclofenac 50mg daily or need other oral or injection form of pain control, are excluded; At the same time, patients with Glucosamine, Chondroitin sulfate, and muscle relaxants use; sensitivity to medicinal plants; History of receiving oral or topical steroids during the 14 days prior to the study; Corticosteroids injection in the period of 30 days before study; pregnancy, hepatorenal active disease, gastritis, addiction to alcohol and narcotic drugs, skin disease of knee, those receiving antidepressant for chronic pain, Also, people who have mild and intermittent pain that only require non-pharmacological recommendations; New forms of therapies such as hydrotherapy, physiotherapy, start to interfere with the study.

**Age**

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

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee in Biomedical Research, Shahid Beheshti University of Medical Sciences (IR.SBMU.REC

**Street address**

Office of Research Management, Shahid Beheshti University of Medical Sciences, side of Taleghani Hospital, Evin, Shahid Chamran Highway, Tehran

**City**

Tehran

**Postal code**

ایران

**Approval date**

2016-07-03, 1395/04/13

**Ethics committee reference number**

IR.SBMU.REC.1395.2

## Health conditions studied

### 1

**Description of health condition studied**

knee osteoarthritis

**ICD-10 code**

M17

**ICD-10 code description**

Gonarthrosis

## Primary outcomes

### 1

**Description**

pain

**Timepoint**

At the beginning of intervention and 6 weeks after the beginning of intervention

**Method of measurement**

KOOS Pain and VAS

## Secondary outcomes

### 1

**Description**

Knee discomfort

**Timepoint**

At the beginning of intervention and 6 weeks after the beginning of intervention

**Method of measurement**

KOOS Scoring

### 2

**Description**

Stiffness

**Timepoint**

At the beginning of intervention and 6 weeks after the beginning of intervention

**Method of measurement**

KOOS Scoring

**3**

**Description**
Activities and daily living
**Timepoint**
At the beginning of intervention and 6 weeks after the beginning of intervention
**Method of measurement**
KOOS Scoring

**4**

**Description**
Sport and recreation function
**Timepoint**
At the beginning of intervention and 6 weeks after the beginning of intervention
**Method of measurement**
KOOS Scoring

**5**

**Description**
Quality of life
**Timepoint**
At the beginning of intervention and 6 weeks after the beginning of intervention
**Method of measurement**
KOOS Scoring and SF26 WHO

## Intervention groups

**1**

**Description**
Intervention group: Linum usitatissimum seed topical oil 20 drops every 8 hours without massage for 6 weeks, in case of pain, up to 3 tablets of diclofenac 50 mg is permitted
**Category**
Treatment - Drugs

**2**

**Description**
Control group: placebo; paraffin oil with the same method and order of intervention groups and for 6 weeks, in case of pain, up to 3 tablets of diclofenac 50 mg is permitted
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Dr Shariat Panahi Clinic
**Full name of responsible person**
Mohammad Kazem Emami meybodi
**Street address**
No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran
**City**
Tehran

**2**

**Recruitment center**
**Name of recruitment center**
Orthopedic Clinic of Bagheiyatallah Hospital
**Full name of responsible person**
Nematollah Masoudi
**Street address**
**City**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research,Traditional Medicine College of Shahid Beheshti University of Medical S
**Full name of responsible person**
Dr Mahmood Mosadegh
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No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran
**City**
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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**
Vice chancellor for research,Traditional Medicine College of Shahid Beheshti University of Medical S
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

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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)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*