

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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+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 years 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

Tehran

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

Street address

No.8 Shams Alley, Opposite Tavanir St, Vali Asr St, Tehran

City

Tehran

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

Contact

Name of organization / entity

College of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nematollah Masoudi

Position

Ph.D student of Traditional Medicine

Other areas of specialty/work

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Traditional Medicine College of Shahid Beheshti
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Associate Professor

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Position

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Other areas of specialty/work

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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