

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of effectiveness of a topical formulation of linseed oil with Diclofenac gel in patients with mild to moderate knee osteoarthritis

Protocol summary

Summary

This is a Double-Blinded randomized clinical study to compare the effect of a topical formulation of linseed oil with Diclofenac gel in patients with clinical symptoms of knee osteoarthritis. 94 patients after taking signed informed consent, according to American College of Rheumatology classification criteria for osteoarthritis and Kellegren-Lawrence system of classification by the doctor, in the age range 35-70 years are accepted. They will allocate to two arms using block randomization. 100 acetaminophen 500 milligrams tablets also given to the patients to use for pain relief if needed. Drugs will be encoding and without the name.it will be prescribed three times a day for 4 weeks in intervention groups. Patients at the beginning and every 2 weeks from the beginning of the study will be evaluated by the KOOS questionnaire until the forth week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082011341N9**

Registration date: **2017-09-19, 1396/06/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

Name

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Name of organization / entity

Fasa University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Fasa University of Medical Sciences

Expected recruitment start date

2017-10-02, 1396/07/10

Expected recruitment end date

2018-03-01, 1396/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of a topical formulation of linseed oil with Diclofenac gel in patients with mild to moderate knee osteoarthritis

Public title

The evaluation of effectiveness of a topical formulation of linseed oil in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the age between 35-70 years;at least having pain in one knee for past 3 months;recognition of osteoarthritis by the doctor according to American college of rheumatology classification criteria; recognition of grade I to III osteoarthritis by the doctor according to Kellegren-Lawrence(K-L)grading scale;absence of any congenital abnormality in lower extremity;written informed consent for inclusion. Exclusion Criteria: sensitivity and allergy to linseed or diclofenac gel or acetaminophen;skin disease in

knee;patients with secondary osteoarthritis due to other bone joint disorders like rheumatoid arthritis, gout, infected arthritis, metabolic arthritis, traumatic arthritis; joint replacement; oral and topical use of corticostreoid in past 14 days;knee corticosteroid or hyaluronic acid injection in the past 90 days; other articular corticosteroid or hyaluronic acid injection in the past 1 month;topical or oral usage of painkillers in past 3 days;concomitant use of glucosamin or chondroitin sulfate;pregnancy and lactation; alcohol or drug addiction; disability to cooperate in filling the forms (cognitive or language disorder); patients with active peptic ulcer diseases and inflammatory bowl disease(IBD);BMI ≥ 35 kg/m²;physical modality in knee joint in past 2 weeks like physical therapy,acupuncture and Transcutaneous Electrical Nerve Stimulator (TENS).

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Comitmtte of Fasa University of Medical Sciences

Street address

Vice Chancellor of Research and Technology,Fasa University of Medical Sciences,Ebn-Sina square,Fasa

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Fasa

Postal code

Approval date

2017-07-26, 1396/05/04

Ethics committee reference number

IR.FUMS.REC.1396215

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M-17

ICD-10 code description

Gonarthrosis

Primary outcomes

1

Description

Visual analogue scale

Timepoint

At the beginning of intervention,after2 weeks then after 4 weeks from the beginning of intervention

Method of measurement

Asking the patients

Secondary outcomes

1

Description

Function in daily living (ADL)

Timepoint

At the beginning of intervention,after 2 weeks then 4 weeks afterthe beginning of intervention

Method of measurement

KOOS questionnaire

2

Description

Other Symptoms

Timepoint

At the beginning of intervention,after 2 weeks then 4 weeks afterthe beginning of intervention

Method of measurement

KOOS questionnaire

3

Description

pain

Timepoint

At the beginning of intervention,after 2 weeks then 4 weeks afterthe beginning of intervention

Method of measurement

KOOS questionnaire

4

Description

Function in sport and recreation(Sport/Rec)

Timepoint

At the beginning of intervention,after 2 weeks then 4 weeks afterthe beginning of intervention

Method of measurement

KOOS questionnaire

5**Description**

Knee related quality of life(QOL)

Timepoint

At the beginning of intervention,after 2 weeks then 4 weeks afterthe beginning of intervention

Method of measurement

KOOS questionnaire

Intervention groups**1****Description**

linseed oil,three times a day on,topically on painful knee

Category

Treatment - Drugs

2**Description**

Diclofenac gel 1%,three times a day,topically on painful knee

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hamzeh clinic

Full name of responsible person

Dr.Shadan Shirazi Zadeh Mehraban

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research,Fasa University of Medical Sciences

Full name of responsible person

Dr.Mojtaba Farjam

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Vice Chancellor of Research and Technology,Fasa University of Medical Sciences,Ebn-Sina square,Fasa

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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,Fasa University of Medical Sciences

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**

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Full name of responsible person

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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