

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of effectiveness of topical sesame oil with Diclofenac gel in patients with knee osteoarthritis

Protocol summary

Summary

This is a single-Blinded (at the level of researchers and bio-statisticians) randomized clinical study to compare the effects of Sesame Oil with Diclofenac gel on patients with clinical symptoms of knee osteoarthritis. 90 patients after taking signed informed consent according to American college of rheumatology classification criteria are accepted. The main exclusion criteria included: sensitivity to Sesame Oil or Diclofenac gel or celecoxib; unwillingness to continue to participate in the study; joint replacement; concomitant use of glucosamine and chondroitin sulfate; knee corticosteroid or hyaluronic acid injection in the past 3 months; other articular corticosteroid or hyaluronic acid injection in the past 1 month; pregnancy or Lactating women; using oral or topical corticosteroid 14 days ago before study be started. The patient will allocate to two arms using block randomization. Celexib tab 100 milligrams also given to the patients to use for pain relief if needed. Drugs will be encoding and without the name, three times a day for 2 weeks will prescribe to intervention groups. Patients at the beginning and once every 2 week from the beginning of the study will be evaluated for General status of pain, physical function and stiffness of joint by the WOMAC questionnaire until the fourth week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081711341N8**

Registration date: **2017-09-22, 1396/06/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-22, 1396/06/31

Registrant information

Name

Mohammad Hashem Hashempur

Name of organization / entity

Fasa University of Medical Sciences

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Iran (Islamic Republic of)

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hashempurm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Fasa University of Medical Sciences

Expected recruitment start date

2017-10-01, 1396/07/09

Expected recruitment end date

2017-11-20, 1396/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of topical sesame oil with Diclofenac gel in patients with knee osteoarthritis

Public title

The evaluation of effectiveness of topical sesame oil on clinical symptoms in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the age between 30-70 years old; patient's written informed consent for inclusion; diagnosis of osteoarthritis by the orthopedist according

to American College of Rheumatology classification criteria; grade I to III osteoarthritis according to Kellgren-Lawrence system of classification; pain of at least one knee during 3 months ago; no congenital abnormality of lower extremity. Exclusion Criteria: hypersensitivity to Sesame Oil or Diclofenac gel or celecoxib; unwillingness to continue to participate in the study; secondary osteoarthritis due to rheumatologic diseases like rheumatoid arthritis, gout, pseudo gout, infected arthritis, metabolic arthritis, traumatic arthritis; joint replacement; concomitant use of glucosamine and chondroitin sulfate; knee injection of corticosteroid or hyaluronic acid in the past 3 months; other articular corticosteroid or hyaluronic acid injection in the past 1 month; use of oral or topical analgesic drugs 3 days before enrollment; pregnancy or Lactating women; alcohol addiction; drug abuse; using oral or topical corticosteroid 14 days days before enrollment; skin lesions of knee; disability to cooperate in filling the forms (cognitive or language disorder); the patient who use drugs that interact with celexib (e.g. lithium, fluconazole, warfarin, diuretics, ACE inhibitors like captopril, ARBs like losartan); patient with IBD or PUD; obesity (BMI \geq 35 kg/m²); use of physical modalities 2 weeks before enrollment (such as physical treatment, Acupuncture and Transcutaneous Electrical Nerve Stimulator).

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Fasa University of Medical Sciences

Street address

Fasa University of Medical Sciences, Ebnesina square,

Fasa

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Postal code**Approval date**

2016-03-08, 1394/12/18

Ethics committee reference number

IR.FUMS.REC.1394.39

Health conditions studied**1****Description of health condition studied**

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Gonarthrosis

Primary outcomes**1****Description**

General status of pain, physical function and stiffness of patients

Timepoint

At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement

WOMAC questionnaire

Secondary outcomes**1****Description**

Joint stiffness

Timepoint

At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement

WOMAC questionnaire

2**Description**

physical activity

Timepoint

At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement

Asking from patients

3**Description**

Speed of walking

Timepoint

At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement

with measuring time of 8 meters walking

4**Description**

Knee flexion angle

Timepoint

At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement

by using of standard goniometer

5**Description**

The need for celecoxib 100 milligrams tablets

Timepoint

At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement

Asking from patients

6**Description**

Knee pain

Timepoint

At the beginning of intervention and 2 week, 4 weeks after the beginning of intervention

Method of measurement

VAS ruler, WOMAC questionnaire

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

Diclofenac 1% topical gel, three times a day on the knee

Category

Treatment - Drugs

2**Description**

Sesame oil, three times a day, topically on knee

Category

Treatment - Drugs

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

Hamzeh Clinic

Full name of responsible person

Dr Askari

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Fasa University of Medical Sciences, Ebne sina square, Fasa, Fars, Iran

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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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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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Position

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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