

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of topical Pistacia vera oil on clinical signs and symptom of knee joint osteoarthritis: a randomized and double blind clinical trial

Protocol summary

Study aim

The effect of topical Pistacia vera oil on clinical signs and symptom of knee joint osteoarthritis: a randomized and double blind clinical trial

Design

A double-blind, placebo-controlled clinical trial by simple randomization method

Settings and conduct

Clinical trial will be performed in the first half of the year on osteoarthritis patients referred to Rafsanjan Rheumatology Clinic. Diagnosis is made with the American College of Rheumatology. Pain, morning stiffness, range of motion, and function of patients in each of the three intervention groups will be assessed at the beginning and the end of the study using the Visual Analogue Scale(VAS) and Western Ontario and Mc Master(WOMAC). In order to double-blind the study, Clinical symptoms are assessed by a rheumatologist who is not aware of the type of medication used by each individual.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 45-70 years, average knee pain within 24 hours based on VAS between 4 and 7 and Exclusion criteria: Patients with inflammatory diseases (such as lupus, rheumatoid arthritis, history of brucellosis, etc.), cancer, Symptoms or history of hepatic or renal failure, oral corticosteroid consumption over the past 4 weeks, corticosteroid injection over the past 6 months, fever, consumption of medical herbs continuously, smoking, pistachio allergy, use of food or drug supplements, oral use of other analgesics and other compounds effective in treating osteoarthritis up to 10 days before the study, skin or infectious disease or ulcer at the place of administration, pregnancy

Intervention groups

Patients in group A: pyroxicam gel, in group B: pistachio oil, and in group C, will be used on the basis of Farabi

Main outcome variables

Pain and status of osteoarthritis in terms of morning

stiffness, range of motion and function of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180811040759N1**

Registration date: **2019-09-09, 1398/06/18**

Registration timing: **retrospective**

Last update: **2019-09-09, 1398/06/18**

Update count: **0**

Registration date

2019-09-09, 1398/06/18

Registrant information

Name

Mitra Abbasifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0040

Email address

dr.mabbasifard@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical Pistacia vera oil on clinical signs and symptom of knee joint osteoarthritis: a randomized and double blind clinical trial

Public title

The effect of topical Pistacia vera oil on knee joint osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 45-70 years diagnosis of knee osteoarthritis according to American College of Rheumatology, approved by rheumatology specialist the average knee pain within 24 hours is based on the linear-visual pain scale (VAS) between 4 to 7

Exclusion criteria:

Patients with inflammatory diseases (such as lupus, rheumatoid arthritis, history of brucellosis, etc.) cancer or chronic diseases symptoms or history of liver or kidney failure oral corticosteroid consumption during the past 4 weeks corticosteroid injection in the last 6 months fever Consumption of medical herbs continuously Smoking pistachio allergy use of food and drug supplements Oral use of other analgesics and other compounds effective in treating osteoarthritis up to 10 days before the study Skin or infectious disease or ulcer at the place of administration pregnancy

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method. Unit: individual, simple random instrument: dice throwing one and two numbers for group A and numbers three and four for group B and numbers five and six for group C and completing groups with this sequence. And hiding using randomly encoded boxes

Blinding (investigator's opinion)

Double blinded

Blinding description

To have double blind study, before the study begins, the drugs will be packaged by someone other than the researcher in the same packages and encoded as A, B, and C. Prescribing by rheumatologist as an A or B or C drug and Delivery is done by someone else

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Ali ibn Abi Talib Square, Ali ibn Abi Talib Hospital

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.RUMS.REC.1397.175

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Knee pain intensity

Timepoint

At the beginning and the end of the study (three months after the beginning of the study)

Method of measurement

The linear-visual scale of pain

2

Description

morning stiffness & Patients' function

Timepoint

At the beginning and the end of the study (three months after the beginning of the study)

Method of measurement

WOMAC questionnaire

Secondary outcomes

empty

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Email

dr.mabbasifard@gmail.com

Intervention groups

1

Description

Intervention group: Group A is used topically in the pyroxicam gel. The treatment duration is 3 months and twice daily. During the study, patients are only allowed to use oral analgesics (7.5 mg of meloxicam) once daily in all groups if needed, and none of the common drugs will be used during this period.

Category

Treatment - Drugs

2

Description

Intervention group: Group B is used topically for pistachio oil. The treatment duration is 3 months and twice daily. During the study, patients are only allowed to use oral analgesics (7.5 mg of meloxicam) once daily in all groups if needed, and none of the common drugs will be used during this period.

Category

Treatment - Drugs

3

Description

Control group: Group C is used topically from the base of Farabi, which is a ready-made and non-effective drug base, along with color for placebo. The treatment duration is 3 months and twice daily. During the study, patients are only allowed to use oral analgesics (7.5 mg of meloxicam) once daily in all groups if needed, and none of the common drugs will be used during this period.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Clinic of Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Mitra Abbasi Fard

Street address

Ali ibn Abi Talib Square, Ali ibn Abi Talib Hospital

City

Rafsanjan

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Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Ali Shamsi Zadeh

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Imam Ali Street, Central Authority

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Fateme nazhadkoorki

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

Contact

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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