

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of topical aqueous extract of pistachio (*Pistacia Vera L.*) pericarp on knee osteoarthritis: A randomized double-blind controlled clinical trial

Protocol summary

Study aim

Study on topical effect of aqueous extract of pistachio pericarp on some clinical signs of knee osteoarthritis in a double-blind clinical trial

Design

A placebo-controlled clinical trial, with parallel, double-blind, randomized groups, on 75 patients. Random blocks will be used for randomization.

Settings and conduct

A double-blind randomized clinical trial will be performed on all patients with knee osteoarthritis at the Rheumatology Clinic in Rafsanjan. The diagnosis of osteoarthritis of the knee is made according to the diagnostic criteria of the American College of Rheumatology. Pain, morning dryness, range of motion and performance of patients in all three intervention groups at the beginning and end of the study will be assessed using the e Visual Analogue Scale (VAS) and WOMAC criteria. Topical cream of pistachio pericarp aqueous extract is prepared by a pharmacologist in a special scientific method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 45-70 years old, diagnosis of knee osteoarthritis based on American College of Rheumatology (ACR) criteria, which was approved by a specialist in rheumatology, and the presence of moderate knee pain within 24 hours based on Visual Pain Scale (VAS) to 4-7 cm. Exclusion criteria: Patients with inflammatory diseases (such as lupus, rheumatoid arthritis, a history of brucellosis, etc.), cancer or other serious diseases, symptoms or history of liver or kidney failure, taking oral corticosteroids in the past 4 weeks, corticosteroid injection during the last 6 months, allergy to pistachios

Intervention groups

Individuals will be randomly participated in this study in one of three groups: A: Piroxicam gel, B: aqueous extract of pistachio pericarp (topical ointment) and C: Base cream Farabi

Main outcome variables

Intensity of knee pain; Knee performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210912052445N1**

Registration date: **2021-11-13, 1400/08/22**

Registration timing: **prospective**

Last update: **2021-11-13, 1400/08/22**

Update count: **0**

Registration date

2021-11-13, 1400/08/22

Registrant information

Name

Soudeh Khanamani Falahati-pour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical aqueous extract of pistachio (Pistacia Vera L.) pericarp on knee osteoarthritis: A randomized double-blind controlled clinical trial

Public title

The effect of aqueous extract of pistachio pericarp on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age 45-70 years old diagnosis of knee osteoarthritis will be based on American College of Rheumatology (ACR) criteria, which will be approved by a specialist in rheumatology the presence of moderate knee pain within 24 hours will be based on Visual Pain Scale (VAS) to 4-7 cm

Exclusion criteria:

Patients with inflammatory diseases (such as lupus, rheumatoid arthritis, a history of brucellosis, etc.) cancer or other serious diseases symptoms or history of liver or kidney failure Taking oral corticosteroids in the past 4 weeks corticosteroid injection during the last 6 months Fever continuous use of herbs smoking and drugs allergy to pistachios consuming of dietary and medicinal supplements consumption of pistachios during the two weeks before the start of the test Regular daily use of painkillers and very advanced disease use of other topical drugs at the site of drug use oral use of other analgesics and other effective compounds in the treatment of osteoarthritis up to 10 days before the study skin or infectious disease or wound at the site of drug use pregnancy

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Since the three groups need to have the same sample size, the (Restricted randomization) method will be used to divide people into three groups. In this way, first a number is assigned to each patient (1 to 75), then the number of each patient is written on a piece of paper and the papers will be folded so that the number can not

be seen on them, all the papers in one container pour and after mixing, divide them into three equal groups and pour in three separate containers (Each container will contain 25 pieces), and finally, using a coin toss, consider one container as group A, another B and the other as group C.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to double-blind controlled clinical trial the study, before starting the study, the drugs will be placed in the same packages by someone other than the researcher and will be coded as A, B and C. The drug is prescribed by a rheumatologist in the form of drug A or B or C and the drug is delivered by another person. Evaluation of clinical symptoms is performed by an internal resident who does not know the type of drug used by each individual.

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

Pistachio Safety Research Center, Food & Drug Deputy Building, Rafsanjan University of Medical Sciences, Next to the St.22, Taleghani Avenue, Rafsanjan, Iran

City

Rafsanjan

Province

Kerman

Postal code

7717735979

Approval date

2021-06-26, 1400/04/05

Ethics committee reference number

IR.RUMS.REC.1400.057

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

Intensity of knee pain on Visual Analogue Scale (VAS)

Timepoint

Before intervention-8 weeks after intervention

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Knee performance in Western Ontario and Mc Master (WOMAC)

Timepoint

Before intervention-8 weeks after intervention

Method of measurement

Questionnaire Western Ontario and Mc Master (WOMAC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A: Piroxicam gel, Topical application twice a day, 8 weeks, Drug massage (3-5 minutes)

Category

Treatment - Drugs

2

Description

Intervention group: B: aqueous extract of pistachio pericarp (topical ointment), Topical application twice a day, 8 weeks, Drug massage (3-5 minutes)

Category

Treatment - Drugs

3

Description

Control group: C: Farabi base ointment for placebo, Topical application twice a day, 8 weeks, Drug massage (3-5 minutes)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Clinic of Rafsanjan University of Medical Sciences

Full name of responsible person

Mitra Abbasifard

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Ali Ibn Abitaleb Square, Hazrat Ali Ibn Abitaleb Hospital (Ali)

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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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

Soudeh Khanamani Falahati-pour

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available