Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
+98 34 3428 2703

Email address
s.falahatipour@rums.ac.ir

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
Street address
Ali Ibn Abitaleb Square, Hazrat Ali Ibn Abitaleb Hospital (Ali)
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0038
Fax
+98 34 3428 0038
Email
dr.mabbasifard@gmail.com
Web page address
http://psrc.rums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsizadeh
Street address
mam Ali St., Central Organization
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0038
Fax
+98 34 3428 7910
Email
info@rums.ac.ir
Web page address
http://www.rums.ac.ir/
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

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

Phone
+98 34 3428 2703

Fax
+98 34 3428 2706

Email
s.falahatipour@rums.ac.ir

Web page address
http://psrc.rums.ac.ir/

Person responsible for scientific 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.

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City
Rafsanjan

Province
Kerman

Postal code
7717735979

Phone
+98 34 3428 2705

Fax
+98 34 3428 2706

Email
s.falahatipour@rums.ac.ir

Web page address
http://psrc.rums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Soudeh Khanamani Falahati-pour

Position
Associate professor

Latest degree
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Other areas of specialty/work
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Phone
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Fax
+98 34 3428 2706

Email
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Web page address
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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