Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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)

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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

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
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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

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Fatemenezhadkoorki

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medical student

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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