Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Topical Pistacia Atlantica Oil on some Clinical of Knee Osteoarthritis: a Randomized and Double Blind Clinical Trial

Protocol summary

Study aim

Determining the local effect of caraway oil on some clinical symptoms of knee osteoarthritis: a double-blind clinical trial study.

Design

The study is a parallel- groups, randomized, double-blind, and controlled clinical trial. Phase 3 on 50 patients in three groups.

Settings and conduct

A clinical trial will be conducted in 2019 on osteoarthritis patients referred to the rheumatology clinic in Rafsanjan. Diagnosis is made by the American College of Rheumatology. The pain level of the patients will be evaluated at the beginning and end of the study with the help of a visual analogue scale (VAS). This criterion is a 10 cm ruler that the patient is asked to indicate the intensity of his pain from 0 to 10. WOMAC (Western Ontario and Mc Master) criteria will be used to check the performance of patients.

Participants/Inclusion and exclusion criteria

All patients with osteoarthritis between the ages of 50-70. Inclusion: The diagnosis of knee osteoarthritis is based on the the American College of Rheumatology. Average knee pain during 24 hours based on the linear-visual pain scale (VAS) 4-7 cm. Exclusion: Patients suffering from inflammatory diseases and cancer, liver or kidney failure, Taking oral corticosteroids during the last 4 weeks, corticosteroids injection in the last 6 months. fever, Consuming medicinal plants , Allergy to the Pistacia Atlantica, unwillingness to continue in the study, Failure to comply with the study protocol, Side effects may be caused by Pistacia Atlantica by oil.

Intervention groups

Intervention group A: Group A will use piroxicam gel topically. Intervention group B: Group B will use topical Pistacia Atlantica oil to relieve pain. Control group: In group C, paraffin will be used for placebo and to compare their effects

Main outcome variables

Pain and status of osteoarthritis range of motion, morning dryness and physical function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190128042525N7**
Registration date: **2024-11-01, 1403/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-01, 1403/08/11**
Update count: **0**

Registration date

2024-11-01, 1403/08/11

Registrant information

Name

Gholamreza Bazmandegan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3428 0185

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2025-01-19, 1403/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Topical Pistacia Atlantica Oil on some Clinical of Knee Osteoarthritis: a Randomized and Double Blind Clinical Trial

Public title
Effect of Topical Pistacia Atlantica Oil on some Clinical symptoms of Knee Osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 50-70 The diagnosis of knee osteoarthritis is based on the criteria of the American College of Rheumatology, which is confirmed by a rheumatology specialist. The presence of average knee pain during 24 hours based on the linear-visual pain scale (VAS) between 4 and 7 cm.

Exclusion criteria:
Patients suffering from inflammatory diseases (such as lupus, rheumatoid arthritis, history of brucellosis, etc.) Cancer or serious diseases, symptoms or history of liver or kidney failure, Taking oral corticosteroids during the last 4 weeks corticosteroids injection in the last 6 months. fever Consuming medicinal plants continuously Allergy to the Pistacia Atlantica unwillingness to continue participating in the stud Failure to comply with the study protocol Observing any side effects that the patient thinks are caused Pistacia Atlantica by oil.

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, in order to reduce bias and increase the reliability of the results, patients were assigned to three groups using a table of random numbers. In this way, the researcher first considered the direction of reading the numbers as a left-to-right convention. Then he assigned numbers 00-30 to group A, numbers 31-60 to group B, and numbers 61-90 to group C. Then the researcher put his hand on one of the numbers and recorded the numbers from left to right and assigned them to different groups. To hide the random allocation (allocation concealment), drugs and placebo were placed in the same packages and coded as A, B, and C. In the randomization process, the person involved in creating the randomization plan was separate from other researchers, to reduce possible bias.

Blinding (investigator's opinion)
Double blinded

Blinding description
Before starting the study, the drugs will be placed in the same packages by someone other than the researcher and coded as A, B, and C. Medicines are prescribed by a rheumatology specialist in the form of medicine A or B or C and the medicine is delivered by another person. The evaluation of clinical symptoms is done by the internal resident, who does not know the type of medicine used by each person, and based on the relevant protocol (which is explained below).

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 Abitaleb Blvd

City
Rafsanjan

Province
Kerman

Postal code
7717937555

Approval date
2019-11-11, 1398/08/20

Ethics committee reference number
IR.RUMS.REC.1398.143

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
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: Group A will use piroxicam gel topically. The duration of treatment is 3 months and twice a day. In addition, patients will be allowed to use oral analgesics drugs as needed to relieve their pain.
Category
Treatment - Drugs

2

Description
Intervention group B: Group B will use topical Pistacia Atlantica oil to relieve pain. The duration of treatment is 3 months and twice a day. During the study, patients are only allowed to use oral painkillers once a day if needed, and none of the common drugs will be used during this period.
Category
Treatment - Drugs

3

Description
Control group: In group C, paraffin will be used for placebo and to compare their effects.The duration of treatment is 3 months and twice a day. During the study, patients are only allowed to use oral painkillers once a day 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
Gholamreza Bazmandegan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
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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
Gholamreza Bazmandegan
Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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