Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

The effect of topical basil vera oil on clinical signs of knee joint osteoarthritis

Protocol summary

Study aim
The effect of topical basil vera oil on clinical signs of knee joint osteoarthritis

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 42 patients. The randomization type is simple

Settings and conduct
Patients with osteoarthritis in Rafsanjan Rheumatology Clinic use the oil topically twice daily for 3 months for time 3 to 5 minutes. In order to double-check the study, before starting the study, drugs will be placed in the package by someone other than the researcher. The delivery of the medicine will be done by someone else. Clinical symptoms are evaluated by a rheumatologist who is unaware of the type of medication being taken by each person. Patients are followed up by visiting the clinic on a weekly basis. The data analyzer will also be unaware of the type of drug used by each person. Patients' pain levels will be assessed at the beginning and end of the study using a linear-visual scale.

Participants/Inclusion and exclusion criteria
Entry Criteria: Diagnosis of knee osteoarthritis and its confirmation by a rheumatologist, as well as moderate knee pain Withdrawal criteria include: having certain diseases, taking medication, pregnancy, not following the study protocol

Intervention groups
Group A topically uses piroxicam gel, group B uses basil oil, and group C uses a Farabi base that is a medicinal base that is ready and ineffective, along with sesame oil

Main outcome variables
Knee pain level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200507047338N1**
Registration date: **2021-04-22, 1400/02/02**
Registration timing: **retrospective**

Last update: **2021-04-22, 1400/02/02**
Update count: **0**

Registration date
2021-04-22, 1400/02/02

Registrant information

Name
Mohammad Hatamian

Name of organization / entity

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Iran (Islamic Republic of)

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mohammadhatamian974@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2020-11-21, 1399/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of topical basil vera oil on clinical signs of knee joint osteoarthritis

Public title
Evaluation of the effect of basil oil on knee osteoarthritis

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of knee osteoarthritis based on the criteria American College of Rheumatology, which is approved by a rheumatologist Average knee pain within 24 hours based on linear-Visually scale of pain between 4 and 7 cm Age limit between 45 and 70 years
Exclusion criteria:
Patients with inflammatory diseases, cancer, or serious illnesses Symptoms or history of liver or kidney failure Oral corticosteroids for the past 4 weeks or corticosteroid injections for the past 6 months fever Consumption of medicinal plants continuously drug using Sensitivity to basil Lack of willingness to continue participating in the study Failure to comply with the study protocol observation the side effects of basil oil Taking supplements and medications, take regular daily painkillers, and be very advanced Using of other topical medications at the use drug site Oral use of other analgesics and other compounds effective in the treatment of osteoarthritis up to 10 days before the study Skin ill 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

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple crash Random allocation with hexagonal blocks Patients are divided into three groups of control (piroxicam), intervention (basil) and placebo (paraffin) by using random allocation with hexagonal blocks. In this way, the control group is assigned the letter A, the intervention group is assigned the letter B, and the placebo group is assigned the letter C, and in six blocks with the letters A, B, and C, the states ABCABC, AABBCC, CBAACB, ABCCBA, CCABAB, AACCBB And .. it is written on separate sheets and thrown into the container and one of the sheets is randomly taken out of the container and the composition of the writing is written on it and returned to the container. Because the sample size in this study is 126 people, this operation will be repeated 21 times and each time the composition written on the sheet will be noted following the previously written composition. This procedure is performed by the student and the day before the random assignment, so patients and the rheumatologist do not know how people are in each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Before starting the study, the drugs will be packaged by someone other than the researcher The drug is delivered by someone other than a rheumatologist The data analyst will also be unaware of the type of drug used by each person
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
Central Organization,Imam Ali Boulevard,Rafsanjan
City
rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2020-08-16, 1399/05/26
Ethics committee reference number
IR.RUMS.REC.1399.128

Health conditions studied

1

Description of health condition studied
knee Osteoarthritis
ICD-10 code
M17.10
ICD-10 code description
Unilateral primary osteoarthritis, unspecified knee

Primary outcomes

1

Description
Average knee pain
Timepoint
Before the study, one and three months later
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Piroxicam gel prepared from Rafsanjan pharmacy is used topically twice a day for three months for 3 to 5 minutes on the sore spot.
Category
Treatment - Drugs

2

Description
Intervention group1: To make the cream, using basil oil, By cold extraction method , which is a simple method and preserves the oil. 24 hours in one kilogram of sesame oil with indirect heat at 65 degrees Celsius, then apply the oil by filtering for three months and twice a day for 3 to 5 minutes topically.
Category
Rehabilitation

3

Description
Intervention group2:Cream is prepared from Farabi base and sesame oil, which is considered as a placebo for this trial, and it is used topically twice a day for three months for a period of 3 to 5 minutes.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology Clinic of Rafsanjan
Full name of responsible person
Dr. Mitra Abbasi fard
Street address
No. Ali ibn Abi taleb Hospital., Mofteh Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
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No. Vice Chancellor for Research and Technology of the Central., Organization of Rafsanjan University of Medical Sciences and Health Services., Imam Ali Blvd
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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
Mohammad Hatamian
Position
Student
Latest degree
A Level or less
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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

Not applicable

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

Not applicable

Data Dictionary

No - There is not a plan to make this available