

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of lavender oil on some clinical symptoms of patients with knee osteoarthritis referred to the rheumatology clinic : a double blind randomised control trial

Protocol summary

Study aim

Determining the effect of lavender oil on a number of clinical symptoms of knee osteoarthritis patients who referred to the rheumatology clinic of Ali Bin Abi Taleb Hospital in Rafsanjan in 2023

Design

Clinical trial with control group and double-blind with simple randomization method, phase 3 on 105 patients.

Settings and conduct

A clinical trial will be conducted in 1401 on osteoarthritis patients referring to the rheumatology clinic of Rafsanjan city. Diagnosis is made by the American College of Rheumatology. The amount of pain, morning dryness, range of motion and performance of patients in all three intervention groups at the beginning and end of the study, with the help of (VAS) and (WOMAC). Double blind 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

Age 45-70 years, the diagnosis of osteoarthritis of the knee is based on the diagnostic criteria of the ACR and the rheumatologist's diagnosis, existence of moderate pain in the knee during 24 hours based on the linear-visual scale of pain between 4-7 cm, Allergy to lavender Reluctance to continue participating in the study Non-compliance with the study protocol Observing any side effects caused by lavender in the patient's opinion

Intervention groups

The participants are divided into three groups of 35 people A, B and C. In group A prepared paraffin oil without effect (placebo group), in group B lavender oil (intervention group) and in group C piroxicam gel (control group). The duration of the treatment is one month and the medicine is used topically once a day.

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: **IRCT20180811040759N4**

Registration date: **2023-03-30, 1402/01/10**

Registration timing: **prospective**

Last update: **2023-03-30, 1402/01/10**

Update count: **0**

Registration date

2023-03-30, 1402/01/10

Registrant information

Name

Mitra Abbasifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0040

Email address

dr.mabbasifard@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lavender oil on some clinical symptoms of patients with knee osteoarthritis referred to the rheumatology clinic : a double blind randomised control trial

Public title

Effect of lavender oil on some clinical symptoms of patients with knee osteoarthritis referred to the rheumatology clinic : a double blind randomised control trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 45-70 years The diagnosis of osteoarthritis of the knee is based on the diagnostic criteria of the American College of Rheumatology and the confirmation of the rheumatologist's diagnosis by a rheumatologist
Existence of moderate pain in the knee during 24 hours based on the linear-visual scale of pain between 4-7 cm

Exclusion criteria:

Allergy to lavender Reluctance to continue participating in the study Non-compliance with the study protocol
Observing any side effects caused by lavender in the patient's opinion

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into three groups of 35 people, A, B, and C, using a simple randomization method (random number table). In group A, prepared paraffin oil without effect (placebo group), in group B, topical lavender oil (intervention group) and in group C, piroxicam gel (control group).

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to make the study double-blind, before the start of the study, the drugs are coded by someone other than the evaluator (secretary). Drug grouping and prescription is done by the rheumatology subspecialist in the form of drug A or B or C and drug delivery is done by another person (secretary). In addition, the analyzer is unaware of the grouping method and the drug used (double blind). In the placebo group, Paraffin oil, which is a ready-made pharmaceutical base without any effect, is

used along with a color similar to lavender for placebo. The color of drug and placebo and the vials containing them are completely similar.

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

2023-02-20, 1401/12/01

Ethics committee reference number

IR.RUMS.REC.1401.225

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) And WOMAC index

Secondary outcomes

empty

Intervention groups

dr.mabbasifard@rums.ac.ir

1

Description

Control group: Group A (35 people) of prepared paraffin oil and without effect (placebo group), the form and type of medicine are the same. The duration of the treatment is 3 months, massage for 3 to 5 minutes daily. During the study, patients in all groups were only allowed to use non-anti-inflammatory oral pain relievers (such as Meloxicar 7.5 mg tablets) once a day as needed.

Category

Placebo

2

Description

Intervention group: group B (35 people) topical lavender oil will be used. The duration of the treatment is 3 months, massage for 3 to 5 minutes daily. During the study, patients are only allowed to use oral painkillers (meloxicar 7.5 mg tablets) once a day in all groups if needed.

Category

Treatment - Drugs

3

Description

Intervention group: Group C (35 people) uses piroxicam gel (control group). The duration of the treatment is one month and the medicine is used topically once a day. The duration and amount of daily drug use are the same in the groups. During the study, patients were only allowed to use oral painkillers (meloxicar 7.5 mg tablets) once a day throughout

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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Emam Ali Ave, rafsanjan university of medical Sciences

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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?

No

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

Mitra Abbasifard

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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