Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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

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 Meloxifar 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 (meloxifar 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 (meloxifar 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
Street address
Emam Ali Ave, rafsanjan university of medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 updating data

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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