Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of achillea millefolium oil on some clinical symptom of knee joint osteoarthritis: a randomized and double blind clinical trial double-blind study

Protocol summary

Study aim
The effect of achillea millefolium oil on some clinical symptom of knee joint osteoarthritis: a randomized and double blind clinical trial double- blind study

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 81 patients, for randomization a random number table was used

Settings and conduct
Clinical trial will be performed in 1401 on osteoarthritis patients referred to the Rheumatology Clinic of Rafsanjan. Patients will be evaluated at the beginning of the study and one and two months after the intervention using the Visual Analogue Scale (VAS) and the WOMAC index. Since the study is double-blind, the evaluation of clinical symptoms is performed by a rheumatologist who is not aware of the type of drug used by each individual.

Participants/Inclusion and exclusion criteria
Inclusion:Age 45-70 years, informed consent to participate in the study, moderate to severe pain intensity visual linear scale of pain, diagnosis of knee osteoarthritis based on the American College of Rheumatology diagnostic criteria and confirmation of rheumatologist diagnosis by rheumatologist, moderate pain In the knee within 24 hours on a linear-visual scale pain between 4-7 cm

Intervention groups
Participants will be divided into three groups: group 1 (27 people) using achillea millefolium oil, group 2 (27 people) placebo and group 3 (27 people) receiving Piroxicam gel.

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: **IRCT20180811040759N3**
Registration date: **2022-06-19, 1401/03/29**
Registration timing: **prospective**

Last update: **2022-06-19, 1401/03/29**
Update count: **0**

Registration date
2022-06-19, 1401/03/29

Registrant information

Name
Mitra Abbasifard

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3428 0040

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-01, 1401/04/10

Expected recruitment end date
2022-09-01, 1401/06/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of achillea millefolium oil on some clinical

symptom of knee joint osteoarthritis: a randomized and double blind clinical trial double- blind study

Public title
The effect of achillea millefolium oil on some clinical symptom of knee joint osteoarthritis: a randomized and double blind clinical trial double- blind study

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Awareness consent to participate in the study Moderate to severe pain intensity visual linear scale of pain 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:
Reluctance to continue participating in the study Non-compliance with the study protocol Observe any side effects that the patient thinks were caused by yarrow oil after the start of the study Taking vitamin, mineral or other nutritional supplements and taking painkillers

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: **81**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a table of random numbers, they are randomly divided into one of three groups: the treatment group (receiving achillea millefolium oil (Oil Seed Company)), the control group (paraffin) and the receiving group of piroxicam gel.

Blinding (investigator's opinion)
Double blinded

Blinding description
Controlled double-blinds (patient not knowing about and completing evaluation of checklists of the type of drug used) will be performed.The duration of the massage is 3 to 5 minutes daily and the duration of taking the medicine is 2 months.The drugs are coded by someone other than the investigator and will be delivered to the Physician. Clinical examinations and confirmation of the disease are performed by a rheumatologist and subsequent evaluations are performed under the supervision of a rheumatologist and by an internal resident who will be unaware of the groups.

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
2022-04-13, 1401/01/24

Ethics committee reference number
IR.RUMS.REC.1401.012

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 (two months after the beginning of the study)

Method of measurement
Visual Analogue Scale (VAS) And WOMAC index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group 1 (27 Individuals) will use achillea millefolium oil. The treatment duration is 2

months, massage 3 to 5 minutes daily. During the study, patients in all groups, are only allowed to use oral analgesics without anti-inflammatory effect such as acetaminophen once daily if needed

Category

Treatment - Drugs

2

Description

Control group: Group 2 (Placebo) (27 individuals). The form and type of the drug is the same. The treatment duration is 2 months, massage 3 to 5 minutes daily. During the study, patients in all groups, are only allowed to use oral analgesics without anti-inflammatory effect such as acetaminophen once daily if needed

Category

Placebo

3

Description

Intervention group: Group 3 will receive Piroxicam gel. The treatment duration is 2 months, massage 3 to 5 minutes daily. During the study, patients in all groups, are only allowed to use oral analgesics without anti-inflammatory effect such as acetaminophen once daily if needed.

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

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

Mitra Abbasifard

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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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