Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of hemp seed oil on clinical symptoms in patients with Knee osteoarthritis referred to the Rheumatology Clinic of Rafsanjan in 2022: A randomized, double-blind, control trial

Protocol summary

Study aim

Topical effect of cannabis oil on some clinical signs of knee osteoarthritis in patients referred to Rafsanjan Rheumatology Clinic in 2022: a double-blind clinical trial

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 126 patients, stratified randomization was used for randomization.

Settings and conduct

clinical trial, will be performed on osteoarthritis patients referred to the Rheumatology Clinic in Rafsanjan in 2022, Patients will be evaluated at the beginning of the study and one to two months after the intervention using the Visual Analogue Scale (VAS) and the WOMAC index. In order to double-blind the study, 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

Inclusion: Age 45-70 years diagnosis of knee osteoarthritis according to American College of Rheumatology, approved by rheumatology specialist the average knee pain within 24 hours is based on the linear-visual pain scale (VAS) between 4 to 7. Exclusion: Patients with inflammatory diseases, serious diseases, history of liver or kidney failure, oral corticosteroids, smoking and drug use, unwillingness to continue the study, non-compliance with the study protocol, Medical supplements use of analgesics, Skin or infectious disease at the site of pregnancy medication

Intervention groups

Participants will be divided into three groups: group 1 (42 people) using Cannabis oil, group 2 (42 people) placebo and group 3 (42 people) receiving diclofenac gel.

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

Hemp seed oil is used in this research and method has changed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180811040759N2**
Registration date: **2022-04-05, 1401/01/16**
Registration timing: **prospective**

Last update: **2023-07-01, 1402/04/10**
Update count: **1**

Registration date

2022-04-05, 1401/01/16

Registrant information

Name

Mitra Abbasifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0040

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of hemp seed oil on clinical symptoms in patients with Knee osteoarthritis referred to the Rheumatology Clinic of Rafsanjan in 2022: A randomized, double-blind, control trial

Public title
Effect of hemp seed oil on clinical symptoms in patients with Knee osteoarthritis referred to the Rheumatology Clinic of Rafsanjan in 2022: A randomized, double-blind, control trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 45-70 years The diagnosis of osteoarthritis of the knee according to the criteria of the American College of Rheumatology, which is confirmed by a specialist in hematology The presence of moderate knee pain within 24 hours based on linear-visual pain scale (VAS) between 4 7 cm Completing the informed consent form

Exclusion criteria:
Patients with inflammatory diseases (such as lupus, rheumatoid arthritis, history of brucellosis, etc.) Cancer or chronic diseases Symptoms or history of liver or kidney failure Oral corticosteroid consumption during the past 4 weeks Corticosteroid injection in the last 6 months fever Consumption of medical herbs continuously Smoking and drug abuse Allergy to hemp seed oil Observe any side effects that the patient thinks are caused by the oil use of food and drug supplements Oral use of other analgesics regularly and advanced disease Use of other topical medications at the site of drug administration Skin or infectious disease or ulcers at the site of pregnancy medication Reluctance to continue participating in the study Failure to comply with the study protocol

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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method. Unit: individual, simple random instrument: dice throwing one and two numbers for group 1 the numbers three and four for group 2 and the numbers five and six for group 3. Completion of groups with this sequence. Concealment is done using randomly coded boxes (allocation concealment).

Blinding (investigator's opinion)
Double blinded

Blinding description
The Physician and the patients will not be aware of the contents of the oil (double-blind). 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

City
Rafsanjan

Province
Kerman

Postal code
7737937555

Approval date
2022-01-23, 1400/11/03

Ethics committee reference number
IR.RUMS.REC.1400.234

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 (30 people) will use Cannabis oil. The treatment duration is 2 months, massage 3 to 5 minutes daily. During the study, patients are only allowed to use oral analgesics (7.5 mg of meloxicam) once daily in all groups if needed, and none of the common drugs will be used during this period.

Category

Treatment - Drugs

2

Description

Control group: Group 2 (Placebo) (30 people). 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 are only allowed to use oral analgesics (7.5 mg of meloxicam) once daily in all groups if needed, and none of the common drugs will be used during this period.

Category

Placebo

3

Description

Intervention group: Group 3 will receive Diclofenac gel. The treatment duration is 2 months, massage 3 to 5 minutes daily. During the study, patients are only allowed to use oral analgesics (7.5 mg of meloxicam) once daily in all groups if needed, and none of the common drugs will be used during this period.

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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Ali ibn Abi Talib Square, Ali ibn Abi Talib Hospital

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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?

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

Dr. Mitra Abbasifard

Position

Assistant professor

Latest degree

Specialist

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
Not applicable
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