

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation the effect of a topical product prepared from mustard seed oil in controlling pain and improving the performance of patients with knee osteoarthritis, a double-blind randomized controlled clinical trial

Protocol summary

Knee pain, joint stiffness, patient performance

Study aim

Determining the effectiveness of topical cream from mustard seed oil in controlling pain and improving the performance of patients with knee OA.

Design

The number of 30 patients will be divided into two groups of 15 people according to the randomization table, and the intervention group will receive medicine for 1 month and the control group will receive placebo. This study is a double-blind randomized controlled clinical trial.

Settings and conduct

The location of the study is the Pain Clinic of Imam Reza Clinic affiliated to Shiraz University of Medical Sciences. After examining the patient and confirming the conditions for entering the study and obtaining informed consent, the doctor provides the drug or placebo to the patient. The doctor and the patient are not informed about the type of cream (with or without medicine).

Participants/Inclusion and exclusion criteria

The study is conducted on patients referred to the pain clinic of Imam Reza infirmary. The age range of patients is between 40 and 80 years. With the initial complaint of "knee pain" which was confirmed as "osteoarthritis of the knee joint" in the radiological examination and imaging. Patients with the following underlying diseases are excluded from the study: diabetes Connective tissue diseases Peripheral vascular diseases Alzheimer All kinds of diseases and movement disorders of the lower limbs Psychiatric diseases

Intervention groups

15 patients in the intervention group use mustard oil topical cream on their knees twice a day for 1 month. 15 patients in the control group use a topical cream twice a day containing all the components of the original cream except the active ingredient as a placebo for 1 month.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220812055668N1**

Registration date: **2022-11-16, 1401/08/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-16, 1401/08/25**

Update count: **0**

Registration date

2022-11-16, 1401/08/25

Registrant information

Name

Kimiya Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3630 3337

Email address

kimia.jafari098@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-02, 1401/07/10

Expected recruitment end date

2023-03-30, 1402/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of a topical product prepared from mustard seed oil in controlling pain and improving the performance of patients with knee osteoarthritis, a double-blind randomized controlled clinical trial

Public title

The effect of a topical product prepared from mustard seed oil in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The study is conducted on patients referred to the pain clinic of Imam Reza (AS) Shiraz With the initial complaint of "knee pain" which has been confirmed as "osteoarthritis of the knee joint" in radiological examination and imaging The age range of patients is between 40 and 80 years Patients with ASA class I, II are included in the study The grade of knee abrasion should be grade II-III based on radiological imaging

Exclusion criteria:

Patients with the following underlying diseases are excluded from the study diabetes Connective tissue diseases Peripheral vascular diseases Alzheimer All kinds of diseases and movement disorders of the lower limbs Psychiatric diseases

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 30 patients are randomly divided between two groups of 15 people in a double-blind clinical trial using the block randomization method .This study is a double blind randomized controlled clinical trial. Patients in both the control group and the drug group are entered based on a random number table. For the control group, a topical cream without medicine (cold cream) is used. The doctor and the patient are not informed about the type of cream (containing medicine or without medicine). Determining the sample size and randomization was done with a computer statistical program. The minimum sample size in each group is 15 people.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted in a double-blind manner and only the evaluator will know the results and code of the drug or placebo group. Creams of drug and drug group are completely similar in appearance. The drug and placebo groups will be separated from each other by receiving the code.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

University Research Ethics Committee, 7th Floor, Shiraz University of Medical Sciences, Central Building, Zand ST

City

Shiraz

Province

Fars

Postal code

713451978

Approval date

2022-07-17, 1401/04/26

Ethics committee reference number

IR.SUMS.REC.1401.255

Health conditions studied**1****Description of health condition studied**

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes**1****Description**

knee pain

Timepoint

Before the intervention, 4 weeks and 12 weeks after starting to use the topical product of mustard seed oil

Method of measurement

Changes in scores of VAS and WOMAC questionnaires

2

Description

Joint dryness

Timepoint

Before the intervention, 4 weeks and 12 weeks after starting to use the topical product of mustard seed oil

Method of measurement

Changes in WOMAC questionnaire scores

3

Description

Patient functionality

Timepoint

Before the intervention, 4 weeks and 12 weeks after starting to use the topical product of mustard seed oil

Method of measurement

Changes in WOMAC questionnaire scores

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who underwent intra-articular injection of Hyaluronic Acid (Hyaluronic Acid Sodium salt 2%) called vijoint one (in the form of a ready-to-inject 60mg/3ml sodium hyaluronate cross-link syringe, manufactured by Apharm, Italy) were included in the study. One week after intra-articular injection of hyaluronic acid, topical medicine (cream prepared from mustard oil) is started to be used for patients. The studied topical product is used twice a day for 1 month. Patients are evaluated at intervals of 4 weeks and 3 months. During the period of examination of the patients, the painkillers are completely identical, including acetaminophen 500 mg, 2 times a day at the time of pain. Patients whose pain does not improve with this amount of medicine, use diclofenac 100 mg tablets.

Category

Treatment - Drugs

2

Description

Control group: In this group, 15 patients use placebo, which is the same cold cream, for 1 month and twice a day in the place of pain (knee). It should be noted that the placebo contains all the components of the original cream except the active ingredient (mustard seed oil)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pain Clinic of Imam Reza (AS) Shiraz Clinic

Full name of responsible person

Mohammad Mehdi Zarshanas

Street address

Imam Reza Clinic, Namazi Sq

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

Fax

+98 71 3647 4673

Email

motahari@sums.ac.ir

Web page address

<https://emamreza.sums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

Street address

Central Organization of Shiraz University of Medical Sciences, Zand ST

City

Shiraz

Province

Fars

Postal code

713451978

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Zarshenas

Position

associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Shiraz

City

Shiraz

Province

Fars

Postal code

713451583

Phone

+98 917 117 3491

Fax**Email**

zarm@sums.ac.ir

Web page address

<https://pharmacy.sums.ac.ir/page-pharmacy/fa/79/form/pld10611>

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Zarshenas

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of pharmacy, Shiraz

City

Shiraz

Province

Fars

Postal code

713451583

Phone

+98 71 3242 4127

Fax

+98 71 3242 4127

Email

ZARM@SUMS.AC.IR

Web page address

<https://pharmacy.sums.ac.ir/page-pharmacy/fa/79/form/pld10611>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Zarshenas

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of pharmacy, Shiraz

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 6122

Email

mmzarshenas@gmail.com

Web page address

<https://pharmacy.sums.ac.ir/page-pharmacy/fa/79/form/pld9914>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

The overall results of the study will be published.

When the data will become available and for how long

After completing the study

To whom data/document is available

Scientific centers

Under which criteria data/document could be used

Conducting scientific studies

From where data/document is obtainable

ZARM@SUMS.AC.IR

What processes are involved for a request to access

data/document

send mail

Comments