Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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

Knee pain, joint stiffness, patient performance

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
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Shiraz
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Postal code
7134814734
Phone
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+98 71 3647 4673
Email
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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
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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

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https://pharmacy.sums.ac.ir/page-pharmacy/fa/79/form/pId10611

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Web page address
https://pharmacy.sums.ac.ir/page-pharmacy/fa/79/form/pId10611

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