Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of tarragon oil on the intensity of pain, dryness and physical function of the knee in people with chronic osteoarthritis.

Protocol summary

Study aim
Determining the effect of using tarragon oil on the amount of pain, joint dryness and physical function of the knee in patients with chronic osteoarthritis.

Design
In this one-blind study, 90 people will be randomly divided into three groups including: tarragon oil group, sesame oil group and control group.

Settings and conduct
90 people who referred to the rheumatologist's office in Shafa doctors building , who met the conditions to enter the study, were selected and randomly assigned to three groups: the first group used tarragon oil made by the Faculty of Pharmacy of Birjand University of Medical Sciences, and the second group used sesame oil. Barij company will use essential oil and the third group will continue their daily life. One-sided blind: the participants will be unaware of the intervention groups and the type of interventions in the other groups.

Participants/Inclusion and exclusion criteria
Entry conditions: age 30-70 years, pain score ≥ 4 in the last 3 months, diagnosis of knee osteoarthritis by a rheumatologist, written and informed consent, no cancer, pregnancy and blood coagulation disease such as hemophilia, no wound above the knee joint and symptoms of acute infection in the knee joint, no skin lesion in the knee area, no surgery for knee joint replacement or steroid injection, no history of allergic reaction to sesame oil or tarragon, no lower limb abnormalities; Conditions of non-entry: consumption of oral and topical steroids within 14 days, alcohol addiction and narcotic drugs, suffering from radiculopathy and neuropathy, patients with musculoskeletal diseases, allergic reaction to sesame oil or products derived from tarragon.

Intervention groups
3 groups: 1- Use of tarragon oil, 2- Use of sesame oil, 3- Control group that will not perform any of the above interventions.

Main outcome variables
Changes in pain score, joint stiffness and knee physical function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220403054396N1**
Registration date: **2023-03-24, 1402/01/04**
Registration timing: **prospective**

Last update: **2023-03-24, 1402/01/04**
Update count: **0**

Registration date
2023-03-24, 1402/01/04

Registrant information
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farzane shafiee
Name of organization / entity
Country
Iran (Islamic Republic of)
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Email address
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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

The effect of tarragon oil on the intensity of pain, dryness and physical function of the knee in people with chronic osteoarthritis.

Public title

The effect of tarragon oil on the intensity of pain, dryness and physical function of the knee in people with chronic osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of knee osteoarthritis by a rheumatologist Pain level based on WOMAC training (mild to moderate pain intensity) People who are able to understand the explanations and complete the interview Age 30-70 years Absence of cancer, pregnancy and blood clotting disease such as hemophilia Not having a wound above the knee joint No signs of acute infection in the knee joint No skin lesions in the knee area No knee replacement surgery or intra-articular steroid injection within 90 days before the study No history of allergic reaction to sesame oil or products derived from tarragon Absence of lower limb abnormalities

Exclusion criteria:

Taking oral and topical steroids within 14 days, alcohol addiction and narcotic drugs Suffering from radiculopathy and neuropathy, patients with musculoskeletal diseases (including rheumatoid, arthritis, septic arthritis, metabolic arthritis, gout and fibromyalgia) Using more than 2 grams a day of acetaminophen or other painkillers such as injectable drugs or other drugs such as glucosamine and Chondroitin sulfate being admitted to the hospital Unwillingness to continue participating in the study Traveling and leaving treatment Allergic reaction to sesame oil or products derived from tarragon

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into three intervention groups (local use of tarragon oil), sesame oil group, and control group, using six permutation blocks that will be generated by Random allocation software. In this way, the selection pattern of patients in three groups is determined. And the type of treatment for each participant will be determined in this way. Then the researcher will explain to the patients how to study and the details of the intervention

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be one-sided blind. In this way, the participants will be unaware of the intervention groups and the type of interventions in the other groups and will only do the intervention that is intended for them upon entering one of the groups.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Ghaffari St., Birjand University of Medical Sciences, Research and Technology Vice-Chancellor

City

birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2022-12-28, 1401/10/07

Ethics committee reference number

IR.BUMS.REC.1401.350

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

pain

Timepoint

before the start of the intervention and immediately after

the intervention, one week later and Three weeks after the intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis questionnaire

2

Description

Joint dryness

Timepoint

before the start of the intervention and immediately after the intervention, one week later and Three weeks after the intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis questionnaire

3

Description

Physical performance

Timepoint

before the start of the intervention and immediately after the intervention, one week later and Three weeks after the intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after explaining the objectives and method of the study to the research patients, if they are willing to cooperate and after obtaining informed consent, the patients will be divided into three intervention groups by using the permutation blocks of six that will be generated with the Random Allocation software. (local use of tarragon oil), the sesame oil group will be the control group. In this way, the selection pattern of patients in three groups is determined. And the type of treatment for each participant will be determined in this way. Then the researcher will explain how to study and the details of the intervention to the patients and explain the method of topical use of oil to each of them. The tarragon plant will first be identified and the corresponding herbarium will be prepared and kept in the Faculty of Pharmacy of Birjand University of Medical Sciences. The method of preparing tarragon oil based on similar articles will be as follows: first, tarragon essential oil will be extracted using Clevenger. The water extract remaining in the Kalunger balloon will be boiled with sesame oil (obtained from Barij Essan Pharmaceutical Company). In this method, water-soluble compounds such as polyphenols and flavonoids are introduced into the oil base. After removing water and remaining oil, essential oil is added to the prepared oil. This method will prevent the loss of volatile compounds. Analysis of tarragon essential oil will be done using a gas chromatograph. The microbial range of the oil is measured and determined based on the standard pharmaceutical pharmacopoeia. If there is a problem, it will be fixed and then he will enter the hospital. Oils will be poured into dark colored containers at the rate of 50 cc. After that, the researcher will give a bottle containing 50 cc of tarragon oil and a weekly schedule to each participant in the intervention group. The intervention group applied tarragon oil extract in the amount of 1.5 cc in the affected knee area three times a day, every other day for three weeks, in each of the internal, external, front and back directions of the affected knee so that the oil covers the entire skin of the area. will be used. Before use, the intervention group patients are asked to test the said oil on the inner part of the forearm to make sure there is no skin sensitivity. Also, the contact number of the researcher will be provided to the participants so that they can contact the researcher in case of any allergies or side effects. The study will be done in a certain season. In addition, the researcher will remind the participants through a phone call to remind them how and when to conduct the intervention. In addition, all participants will use the same conventional drugs, including NSAIDs, acetaminophen, etc., prescribed by a rheumatologist. During the study, patients are allowed to use less than 2 grams of acetaminophen tablets per day, and patients are asked to record their daily acetaminophen intake. And in the visits at the end of the first week and the last week, the researcher will record the number of pills taken. Evaluation of research variables and information will be collected using the WOMAC questionnaire at 4 time points. The first collection point is before the intervention, when the questionnaire is presented to the participants. The next time points for data collection are immediately, 1 week after the intervention and 3 weeks after the intervention, which will be completed by the researcher's phone calls with the participants.

Category

Rehabilitation

2

Description

Control group 1: This group does not receive any topical oil during the intervention. The study will be conducted in a specific season. In addition, all participants will use the same conventional drugs, including NSAIDs, acetaminophen, etc., prescribed by a rheumatologist. During the study, patients are allowed to use less than 2 grams of acetaminophen tablets per day, and patients are asked to record their daily acetaminophen intake. And in the visits at the end of the first week and the last week, the researcher will record the number of pills taken. Evaluation of research variables and information will be collected using the WOMAC questionnaire at 4 time points. The first collection point is before use, when the questionnaire is presented to the participants. The next time points are for data collection, immediately, 1 week and 3 weeks later, which will be completed by the

researcher's phone calls with the participants.

Category

Rehabilitation

3

Description

Control group 2: Sesame oil as placebo as well as traditional oil base will be prepared from Barij Essan pharmaceutical company. The researcher will give a bottle containing 50 cc of sesame oil (similar to the bottle containing tarragon oil) and a weekly schedule to each participant in the placebo group. from a similar type of syringe or dropper) in the area of the affected knee three times a day, every other day for three weeks in each direction of the inside, outside, front and back of the affected knee so that the oil covers the entire skin of the area. will be used. Before use, the patients of this group are asked to test the said oil on the inner part of the forearm to make sure there is no skin sensitivity. Also, the contact number of the researcher will be provided to the participants so that they can contact the researcher in case of any allergies or side effects. Before use, patients are asked to test the mentioned oils on the inner part of the forearm to make sure there is no skin sensitivity. Also, the contact number of the researcher will be provided to the participants so that they can contact the researcher in case of any allergies or side effects. The study will be done in a certain season. In addition, the researcher will remind the participants through a phone call to remind them how and when to conduct the intervention. In addition, all participants will use the same conventional drugs, including NSAIDs, acetaminophen, etc., prescribed by a rheumatologist. During the study, patients are allowed to use less than 2 grams of acetaminophen tablets per day, and patients are asked to record their daily acetaminophen intake. And in the visits at the end of the first week and the last week, the researcher will record the number of pills taken. Evaluation of research variables and information will be collected using the WOMAC questionnaire at 4 time points. The first collection point is before the intervention, when the questionnaire is presented to the participants. The next time points for data collection are immediately, 1 week after the intervention and 3 weeks after the intervention, which will be completed by the researcher's phone calls with the participants.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatologist's office in Shafa doctors building in Birjand city

Full name of responsible person

Zahra Yonesi

Street address

South Khorasan, Birjand, Ghaffari Street, Birjand University of Medical Sciences - Faculty of Nursing and Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellery of Technology And Research of Birjand University of Medical Sciences

Full name of responsible person

Mohammad Reza Miri

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South Khorasan, Birjand, Ghaffari Street, Birjand University of Medical Sciences - Faculty of Nursing and Midwifery

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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

Vice Chancellery of Technology And Research of Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Farzane Shafiee
Position
Master's student
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Bachelor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
Information on the main outcome will be available
When the data will become available and for how long
Access starts 6 months after the results are published
To whom data/document is available
researchers
Under which criteria data/document could be used
.
From where data/document is obtainable
farzane_shafiee97@yahoo.com
What processes are involved for a request to access data/document
.
Comments