

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Topical effect of tarragon oil extract on pain intensity, dryness and physical function of knee joint in patients with chronic osteoarthritis

#### Protocol summary

2021-12-11, 1400/09/20

#### Study aim

Determination of local effect of tarragon oil extract on pain intensity, dryness and physical function of knee joint in patients with chronic osteoarthritis

#### Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 3 on 90 patients. To randomize the draw was done with 3 cards

#### Settings and conduct

Clinical trial with control group, with parallel groups, one-way blind (participant), randomized, phase 3 on 90 patients. To randomize the draw was done with 3 cards.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Confirmation of knee osteoarthritis by an orthopedic specialist 2. Written and informed consent of the person 3- Age 30-70 years Exclusion criteria History of allergic reaction to sweet almond oil or tarragon-derived products 2. Hospitalization 3. Reluctance to continue participating in the study 4. Travel and leave treatment

#### Intervention groups

Tarragon oil extract

#### Main outcome variables

Pain intensity; Dryness and physical function of the knee joint

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211203053264N1**

Registration date: **2021-12-11, 1400/09/20**

Registration timing: **prospective**

Last update: **2021-12-11, 1400/09/20**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Soheila Abedpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3238 1400

##### Email address

shoaybmohammadi1371@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2021-12-18, 1400/09/27

#### Expected recruitment end date

2022-01-07, 1400/10/17

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Topical effect of tarragon oil extract on pain intensity, dryness and physical function of knee joint in patients with chronic osteoarthritis

#### Public title

Topical effect of tarragon oil extract on pain intensity, dryness and physical function of knee joint in patients with chronic osteoarthritis referred to Taleghani Gonbad Kavous Hospital in 1399

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

**Inclusion criteria:**

Confirmation of osteoarthritis of the knee by an orthopedic specialist Pain score  $\geq 4$  at least in the last 3 months based on the VAS scale People who are able to understand the description and complete the interview Written and informed consent of the person Age 30-70 years No cancer, pregnancy and blood coagulation diseases such as hemophilia No wound above the knee joint No signs of acute infection at the knee joint No serious diseases such as liver disease and kidney failure No history of gastric ulcer disease, and skin lesions in the knee area No surgery to replace the knee joint or inject intra-articular steroids 90 days before the study. Do not suffer from abnormalities related to the lower limbs

**Exclusion criteria:**

1- Taking oral and topical steroids for 14 days, alcoholism and drug addiction Patients with radiculopathy and neuropathy, patients with musculoskeletal diseases (including rheumatoid arthritis, septic arthritis, metabolic arthritis, gout and fibromyalgia) History of allergic reaction to sweet almond oil or tarragon-derived products Use more than 2 grams per day of acetaminophen or other analgesics such as injectable drugs or other drugs such as glucosamine and chondroitin sulfate. Hospitalization Not wanting to continue participating in the study Travel and leave treatment

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were randomly divided into three intervention groups (topical application of 3% tarragon oil extract), sweet almond oil group, and control group. For this purpose, a lottery was conducted with three cards. Treatment methods were marked with three ABC marks on cards and placed in a box. Then, at the time of referral, the participants with the inclusion criteria were asked to remove one card from the box, and the next person removed the remaining two cards and the third person removed the remaining card from the box, and as a result, the type of treatment for each participant was determined. .

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients were randomly divided into three intervention groups (topical application of 3% tarragon oil extract), sweet almond oil group, and control group. For this purpose, a lottery was conducted with three cards. Treatment methods were marked with three ABC marks on cards and placed in a box. Then, at the time of

referral, the participants with the inclusion criteria were asked to remove one card from the box, and the next person removed the remaining two cards and the third person removed the remaining card from the box, and as a result, the type of treatment for each participant was determined. . The researcher then explains to the patients how to study and the details of the intervention, and explains the method of topical use of the oil to each of them. 3% tarragon oil extract with the basis of sweet almond oil and also sweet almond oil was prepared from Barij Essential Oil Company of Kashan.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Birjand School of Medical Sciences and Health Services

**Street address**

South Khorasan, Birjand, Ghaffari St., Central Organization of Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717803077

**Approval date**

2020-07-13, 1399/04/23

**Ethics committee reference number**

IR.BUMS.REC.1399.164

**Health conditions studied**

1

**Description of health condition studied**

Chronic osteoarthritis

**ICD-10 code**

M17

**ICD-10 code description**

Osteoarthritis of knee

**Primary outcomes**

1

**Description**

Intensity of pain

**Timepoint**

One week and three weeks after the intervention

## Method of measurement

WOMAC questionnaire and VAS questionnaire

## 2

### Description

Joint dryness

### Timepoint

One week and three weeks after the intervention

### Method of measurement

WOMAC Questionnaire

## 3

### Description

Joint physical function

### Timepoint

WOMAC Questionnaire

### Method of measurement

One week and three weeks after the intervention

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Patients were randomly divided into three intervention groups (topical application of 3% tarragon oil extract), sweet almond oil group, and control group. For this purpose, a lottery was conducted with three cards. Treatment methods were marked with three ABC marks on cards and placed in a box. Then, at the time of referral, the participants with the inclusion criteria were asked to remove one card from the box, and the next person removed the remaining two cards and the third person removed the remaining card from the box, and as a result, the type of treatment for each participant was determined. . The researcher then explains to the patients how to study and the details of the intervention, and explains the method of topical use of the oil to each of them. 3% tarragon oil extract with the basis of sweet almond oil and also sweet almond oil was prepared from Barij Essential Oil Company of Kashan. The concentration of tarragon oil extract was determined based on literature review. Tarragon oil and sweet almond oil are poured into similar containers of dark opacity. The researcher then gave each participant in the group a bottle containing 40.5 cc of 3% tarragon oil and a weekly schedule. The sweet almond oil group also received a similar bottle containing 40.5 cc of sweet almonds with a weekly schedule. The intervention group applied 1.5 cc of tarragon oil extract and the sweet almond oil group applied 1.5 cc of oil (using a similar syringe or dropper) to the affected knee three times a day, daily for three weeks. In each direction, apply the inside, outside, front and back of the affected knee so that the oil covers the entire skin of the area. The control group did not receive any topical oil during the intervention. Before use, patients of almond oil and

intervention groups are asked to test these oils to ensure skin sensitivity on the inside of the forearm. The researcher's contact number was also provided to the participants to contact the researcher in case of any allergies or side effects. The study was conducted in a specific chapter. In addition, in order to remind the participants how and when to perform the intervention, he reminded the participants by phone that all the participants had similar conventional drugs, including NSAIDs, acetaminophen, etc., which were prescribed by an orthopedic specialist. During the study, patients are allowed to use acetaminophen tablets at a rate of less than 2 grams per day, and patients are asked to record their daily acetaminophen use and the number of tablets to be taken at the end of the first and fourth week visits. Was recorded by the researcher. Evaluation of research and information variables was collected using WOMAC questionnaire and visual scale of VAS pain in 4 time points. The first point is the time of collection before the intervention that the questionnaire is presented to the participants. The next time points for data collection were immediately, 1 week after the intervention and 3 weeks after the intervention, which was completed by the researcher's telephone calls with the participants.

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Taleghani Hospital Gonbad Kavous Clinic

#### Full name of responsible person

Zahra Younesi

#### Street address

South Khorasan, Birjand, Ghaffari St., Birjand

University of Medical Sciences - School of Nursing and Midwifery

#### City

birjand

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#### Postal code

9717803077

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+98 56 3238 1400

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abedpur.512@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Bojnourd University of Medical Sciences

#### Full name of responsible person

Zahra Younesi

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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**

Bojnourd 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

abedpur.0512@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Zahra Younesi

**Position**

استادیار

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Person responsible for general inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Soheila Abedpour

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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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