

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The effect of Olibanum (*Boswellia serrata*) gel on clinical symptoms in patients with Osteoarthritis of the knee - a double-blind, placebo-controlled, randomized trials

Protocol summary

Study aim

The aim of this study was to evaluate the effect of Olibanum gel on clinical symptoms in patients with Osteoarthritis of the knee

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 3 on 78 patients. Excel was used for randomization.

Settings and conduct

Rheumatology Clinic of Rafsanjan Patients who meet the inclusion criteria is included in the study. Physicians, researchers, and patients are blind. Patients are visited in weeks 0 and 4, and questionnaires and forms are completed for follow-ups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 40 and under 70 years of age meet the ACR (*) clinical and radiological criteria. Patients with a diagnosis of osteoarthritis grade 1,2,3. ACR (*): Knee pain + at least 1 of the following 4 criteria Morning dryness less than 30 minutes Crepitus Osteophyte in radiography Criteria for not entering: the history of rheumatoid arthritis, gout, CPPD Existence of uncontrolled cardiovascular disease The existence of malignancy has been proven. Severe kidney disease: Creatinine greater than 3 Mg / DI Receive oral corticosteroids 4 weeks in advance Take NSAIDs with a dose of more than 50 mg daily except aspirin and acetaminophen up to a dose of more than 650 mg. Intra-articular administration of the drug in the previous three months The patient's unwillingness or ability to fill in the text of the questionnaire used in the study Exclusion criteria: the patient's unwillingness to continue participating in the study Out of reach of the patient Complications during treatment (itching or other complications) Existence of severe and unbearable pain in the patient

Intervention groups

Intervention group: Olibanum gel : Control group: placebo

Main outcome variables

BMI; KOOS PAIN; KOOS Light daily activity; KOOS Intense and sports activity; Quality of life; acetaminophen per day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201210049670N1**

Registration date: **2020-12-20, 1399/09/30**

Registration timing: **prospective**

Last update: **2020-12-20, 1399/09/30**

Update count: **0**

Registration date

2020-12-20, 1399/09/30

Registrant information

Name

Roshanak Mokaberinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

mokaberi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2022-01-21, 1400/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Olibanum (Boswellia serrata) gel on clinical symptoms in patients with Osteoarthritis of the knee - a double-blind, placebo-controlled, randomized trials

Public title
The effect of Olibanum (Boswellia serrata) gel on clinical symptoms in patients with Osteoarthritis of the knee

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients more than 40 and less than 70 Patients with a diagnosis of osteoarthritis grade 1,2,3 knee pain Morning knee dryness less than 30 minutes Crepitus Osteophyte in radiography
Exclusion criteria:
History of rheumatoid arthritis, gout, CPPD Existence of uncontrolled cardiovascular disease Proven malignancy Severe kidney disease (creatinine above 3 Mg /DI) Receive oral corticosteroids 4 weeks in advance Take NSAIDs with a dose of more than 50 mg daily except aspirin and acetaminophen up to a dose of more than 650 mg daily Intra-articular administration of the drug in the previous three months The patient's unwillingness or ability to fill in the text of the questionnaire used in the study The patient's unwillingness to continue participating in the study

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups of intervention and control using a simple randomization method prepared by Excel software (table of random numbers).
Randomization unit: individual

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs will be packaged in such a way that the treating physician and patients will not be informed of its contents. (Double blind) Researchers will also be

unaware of the type of ointment until the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak
City
tehran
Province
Tehran
Postal code
1983963113

Approval date
2020-10-12, 1399/07/21

Ethics committee reference number
IR.SBMU.RETECH.REC.1399.632

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
BMI

Timepoint
The beginning of the study

Method of measurement
Weighing with scales and height with meters

2

Description
KOOS questionnaire PAIN

Timepoint
At the beginning of the study and after 4 weeks

Method of measurement

Based on a questionnaire filled out by the patient himself

3

Description

KOOS questionnaire Light daily activity

Timepoint

At the beginning of the study and after 4 weeks

Method of measurement

Based on a questionnaire filled out by the patient himself

4

Description

KOOS questionnaire Intense and sports activity

Timepoint

At the beginning of the study and after 4 weeks

Method of measurement

Based on a questionnaire filled out by the patient himself

5

Description

Quality of Life

Timepoint

At the beginning of the study and after 4 weeks

Method of measurement

Based on a questionnaire filled out by the patient himself

6

Description

Acetaminophen intake per day

Timepoint

At the beginning of the study and after 4 weeks

Method of measurement

Based on biography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Olibanum (*Boswellia serrata*) gel gel; Prepared on the basis of 2%Olibanum. To prepare 100 g of gel, 2 g of frankincense is extracted using propylene glycol solvent: water in a ratio of 80 to 20 is extracted by massaging method. The gel is made using the prepared extract, carbomer 940 (1%), soda and distilled water. Physicochemical and microbial quality control tests are performed on the product.

Category

Treatment - Drugs

2

Description

Control group: placebo; Also, using carbomer 940,

distilled water and titanium dioxide are prepared as dyes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Abbasifard's Clinic

Full name of responsible person

Mitar Abbasifard

Street address

Modarres Ave, Rafasnjān, Iran

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3523 0475

Email

dr.mabbasifard@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

No. 2660: Valiasr St: Shahid Beheshti School of Pharmacy: Tehran

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 0096

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Roshanak Mokaberinejad

Position

Asistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No.8. Shams ali,Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Fax**Email**

mokaberi@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Roshanak Mokaberinejad

Position

Asistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No.8. Shams ali,Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Fax**Email**

mokaberi@sbmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Roshanak Mokaberinejad

Position

Asistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No.8. Shams ali,Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1516745811

Phone

+98 21 8877 3521

Fax**Email**

mokaberi@sbmu.ac.ir

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