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 / Dl 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 /Dl) 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, Rafasnjan, 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