

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effectiveness of frankincense oily lotion containing boswellic acid enriched extract in the treatment of knee osteoarthritis symptoms: a randomized placebo-controlled clinical trial

Protocol summary

Study aim

Evaluation of the effectiveness of frankincense extract in the treatment of knee osteoarthritis

Design

Two arm parallel group randomized placebo-controlled clinical trial, phase 3 on 50 patients. Block randomization method with blocks of 4 will be used for randomization.

Settings and conduct

The study will be performed at the rheumatology clinic of Al-Zahra hospital of Isfahan. The subjects in the experimental and control groups will be instructed to use Boswellia and placebo topical lotions, respectively, 3 times daily for 4 weeks on the knee. The scores of WOMAC osteoarthritis index, visual analogue ascale, and patient global assessment will be determined and recorded before and at the end of intervention and compared between the two groups.

Participants/Inclusion and exclusion criteria

1. Age of 40 - 80 years 2. Osteoarthritis of at least one knee for at least 3 months based on the diagnostic criteria of American College of Rheumatology (ACR) 3. Pain score > 4 based on the visual analogue scale (1 to 10) 4. Grade 2 or 3 of Kellgren-Laurence scale in the knee radiography performed within the past 3 months

Intervention groups

Experimental group: frankincense extract lotion (manufactured by Fardis pharmaceutical company) containing 65% boswellic acid, topical application, 3 times daily, for 4 weeks Control group: placebo lotion (manufactured by Fardis pharmaceutical company), topical application, 3 times daily for 4 weeks

Main outcome variables

Pain severity, knee stiffness, patient performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N14**

Registration date: **2020-09-20, 1399/06/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-20, 1399/06/30**

Update count: **0**

Registration date

2020-09-20, 1399/06/30

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7067

Email address

soltani@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-18, 1399/04/28

Expected recruitment end date

2021-01-17, 1399/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of frankincense oily lotion containing boswellic acid enriched extract in the treatment of knee osteoarthritis symptoms: a randomized placebo-controlled clinical trial

Public title

Effect of Boswellia in treatment of knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age of 40 - 80 years Osteoarthritis of at least one knee for at least 3 months based on the diagnostic criteria of American College of Rheumatology (ACR) Pain score > 4 mm based on the Visual Analogue Scale (VAS) Grade 2 or 3 of Kellgren-Lawrence scale in knee radiography within the past 3 months

Exclusion criteria:

Use of intra-articular glucocorticoids within the past 3 months Use of intra-articular sodium hyaluronate within the past 6 months Use of systemic glucocorticoids (either oral or parenteral) within the past 14 days Having other osteoarticular disorders (e.g., rheumatoid arthritis and gout) Skin disorder in knee region Sensitivity to prescribed topical formulations Knee arthroscopy within the past 3 months Illiteracy Unable to answer the questions Pregnancy Lactation

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study Block Randomization will be used. For this purpose, quadruple blocks will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo lotions will be packaged in completely similar containers and the prescribing physician, data collecting person and patient will be blinded to the content of containers.

Placebo

Used

Assignment

Parallel

Other design features

Randomization will be performed using random number table.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Vice-chancellery for research, Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-07-15, 1399/04/25

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.233

Health conditions studied**1****Description of health condition studied**

Knee osteoarthritis

ICD-10 code

Other prim

ICD-10 code description

M17.1

Primary outcomes**1****Description**

WOMAC Index

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Questionnaire

2**Description**

visual analogue scale (VAS)

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

scoring on the scale

3**Description**

patient global assessment (PGA)

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

scoring on the scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oily lotion of frankincense extract containing 65% boswellic acid (manufactured by Fardis pharmaceutical company), 3 times daily for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo lotion (manufactured by Fardis pharmaceutical company), 3 times daily for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology clinic of Al-Zahra hospital

Full name of responsible person

Rasool Soltani

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Al-Zahra Educational and Therapeutic Center, Soffeh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fardis pharmaceutical company

Full name of responsible person

Valiollah Hajhashemi

Street address

Science and technology of health park of Isfahan university of medical sciences, Valiye-Asr Ave., Kilometer 10 of Isfahan-Shiraz freeway

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farazdaru@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Fardis pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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