Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 31 3792 7067

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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
Isfehan
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

Street address

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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8179154417

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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

Assiciate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Position
Associate professor

Latest degree
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Person responsible for updating data

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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