

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Jujube and Frankincense as complementary on knee osteoarthritis pain relief

Protocol summary

Study aim

Main objective: To determine the effect of Jujube and Frankincense as complementary on knee osteoarthritis pain relief in selected clinics in 2020-2021.

Design

This is a randomized controlled trial (RCT) with parallel design. This RCT is in phase 1-2. Sample size is 30 participants in each group. The participants will be allocated to intervention and control groups using block random assignment by blocks of four.

Settings and conduct

The setting of this study is outpatient rheumatology clinics. After getting written informed consent they assign to the groups of intervention. In the first stage the severity of pain and limitations will be assessed by VAS and WOMAC, then intervention group will receive Jujube and Frankincense for one week. At the end of first week two questionnaire will be filled again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 50 to 70. At least 4 months' history of knee pain. Informed consent for entrance to the study. VAS score less than 4. ESR less than 20. CRP less than 10. Exclusion criteria: History of Corticosteroid in last 3 months. Hyaluronic acid injection in the knee in last 6 months.

Intervention groups

Intervention group receives Jujube and Frankincense as complementary to routine treatment. Control group receives only routine drugs.

Main outcome variables

Pain severity based on VAS and WOMAC questionnaires score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150411021697N2**

Registration date: **2022-12-04, 1401/09/13**

Registration timing: **retrospective**

Last update: **2022-12-04, 1401/09/13**

Update count: **0**

Registration date

2022-12-04, 1401/09/13

Registrant information

Name

Mohammad-Reza Sohrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 9936

Email address

m.sohrabi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Jujube and Frankincense as complementary on knee osteoarthritis pain relief

Public title

Effect of Jujube and Frankincense on knee osteoarthritis pain relief

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 50 to 70 years. Knee pain for the past 4 months. VAS score less than 4. CRP less than 10. ESR less than 20. Informed consent for entrance to the study.

Exclusion criteria:

History of disorders in heart, liver and kidney. Corticosteroid consumption in last 3 months. Hyaluronic acid injection in last 6 months. History of inflammatory diseases in joints. Pregnancy Breast feeding

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the participants will be assigned into two intervention and control groups by random block allocation method with a ratio of 1:1. Blocks of sizes 4 and 6 will be made with different sequences of A and B. They will be lined up in a random series. Finally, the order of the letters A and B will determine the sequence of entering the participants in the two groups. A and B cards will be placed in sealed envelopes with consecutive numbers from 1 to 60. As each participant enters, the envelope corresponding to the participant's number is opened, and their treatment group is determined. Sealedenvelope.com will be used to build the above random chain.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak. Arabi St.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-10-31, 1400/08/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.475

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

Pain severity

Timepoint

Pain severity will be assessed the first and 7th day.

Method of measurement

VAS and WOMAC tools.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment in intervention group will be prescription of pill of Jujube and Frankincense twice daily as a complimentary to other routine analgesic drugs for 7 days. Each pill contains 250 mg Jujube and 100 mg Frankincense. It is made in school of pharmacy at Shahid Beheshti University of Medical Sciences.

Category

Treatment - Devices

2

Description

Control group: This group receives only the routine analgesic drugs for 7 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Nahid Kianmehr

Street address

Tehran villa

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1445613131

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m.r.sohrabi@gmail.com

Web page address

<https://hrmc.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mostafa Rezaie Tavirani

Street address

Velenjak, Arabi St.

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tavirany@yahoo.com

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

Mohammad-Reza Sohrabi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Public Health

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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