

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of Iranian traditional medicine product based on commiphora mukul on patients with osteoarthritis of the knee compared to placebo

Protocol summary

Study aim

Determining the efficacy of commiphora mukul in patients with knee osteoarthritis

Design

Clinical trial with control group with parallel group, randomized double-blind Phase 3 is over 70 patients. For randomization using a simple randomization method and will be done in a double-blind method

Settings and conduct

Eligible individuals will be randomly assigned to participate in the study randomly using simple randomization and easy sampling methods, using the two-way blind method. Drugs and placebo (35 people) The drops contain 30 ml of mimic gum and the same amount of placebo, which are exactly the same color, shape and weight and will be available in similar packages. Each patient should take 15 cc of the drops twice a day for two months and twice a day to blind the study. Before the study begins, the drops are encoded by a person other than the researcher in the same packages as A and B.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 40 to 70 - Knee pain (scal 4-7)

Exclusion criteria: Severe illnesses, treatment with oral corticosteroids for the past 4 weeks, corticosteroid injections for the past 6 months

Intervention groups

The intervention group includes patients who receive the commiphora mukul The control group includes patients receiving placebo

Main outcome variables

The severity of the pain - the degree of inability to function the knee

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200225046612N1**

Registration date: **2020-05-01, 1399/02/12**

Registration timing: **prospective**

Last update: **2020-05-01, 1399/02/12**

Update count: **0**

Registration date

2020-05-01, 1399/02/12

Registrant information

Name

Abolghasem Mirzaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 4440

Email address

abolghasem.mirzaie@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Iranian traditional

medicine product based on commiphora mukul on patients with osteoarthritis of the knee compared to placebo

Public title

Investigating the effect of commiphora mukul on osteoarthritis of the knee

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should be between 40 and 70 years old, Diagnosis of knee osteoarthritis based on the diagnostic criteria of American College of Rheumatology and confirmation of knee osteoarthritis by a rheumatologist using radiography and Kellgren Lawrence criteria The presence of moderate knee pain in the last 24 hours so that according to the Visual Analogue Scale (VAS) the pain is between 4 to 7 cm

Exclusion criteria:

.Cancer or serious illness Symptoms or history of liver or kidney failure Treatment with oral corticosteroids in the last 4 weeks or Corticosteroid injections in the last 6 months fever Consumption of any type of medicinal plant Allergy to commiphora Lack of willingness to continue participating in the study Nonconformity with the study protocol See any side effects Lack of nutritional supplementation and painkillers

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The study will be conducted randomly using simple randomization Based on the table of random numbers will be in one of the two groups of Intervention numbers (35 people) and placebo (35 people).

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the study, the droplets are encoded by a person other than the researcher in the same packages as A and B before the study begins. And all patients are asked to bring their previous drops with them in each visit. Patients and researchers are unaware of the type of medication 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

Kermanshah University of Medical Sciences Research Ethics Committee

Street address

Kermanshah - Beheshti Boulevar

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-03-03, 1398/12/13

Ethics committee reference number

IR.KUMS.REC.1399.104

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M15.0

ICD-10 code description

Primary generalized osteoarthritis

Primary outcomes

1

Description

The severity of the pain

Timepoint

Before the intervention and the next two months

Method of measurement

VAS questionnaire

2

Description

Inability to function

Timepoint

Before the intervention and the next two months

Method of measurement

Koos questionnaire

3

Description

Quality of Life

Timepoint

Before the intervention and the next two months

Method of measurement

Koos questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: twice a day for two months from the extract of commiphora mukul plant, which is prepared by Badrang teb Kuhistan, affiliated to the Science and Technology Park of the Ministry of Science and Technology, according to scientific standards, under the supervision of a traditional pharmacy specialist at a dose of 15 ml.

Category

Treatment - Drugs

2

Description

Control group: Patients with a dose of 15 cc for two months are given a placebo that is similar to the intervention drug

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Fattahi Clinic in Kermanshah

Full name of responsible person

Mohammad Hossein Farzaei

Street address

Building No. 1, Kermanshah University of Medical Sciences(KUMS), Shahid Beheshti Boulevard, Kermanshah

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2

Recruitment center

Name of recruitment center

Mahdieh Rheumatology Subspecialty Clinic

Full name of responsible person

Alireza fazaeli

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the beginning of Eram Boulevard. Shahid Beheshti Medical Center. Ghaem Square hamedan

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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Shahid Beheshti Blvd. - number2 Building of Kermanshah University of Medical Sciences

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Grant name

Research

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Mirzaie abolghasem

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

- Shahid Shiroudi Boulevard - Daneshgah Street -
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Science Committee

Latest degree

Ph.D.

Other areas of specialty/work

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

Kermanshah University of Medical Sciences

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Mirzaie abolghasem

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total data

When the data will become available and for how long

6 months after printing

To whom data/document is available

University and industrial institutions

Under which criteria data/document could be used

Treatment

From where data/document is obtainable

Abolghasem Mirzaei Kermanshah University of Medical
Sciences

What processes are involved for a request to access data/document

By email

Comments

