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)

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+98 81 3821 4440

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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 osteoartritis
ICD-10 code
M15.0
ICD-10 code description
Primary generalized osteoarthrosis

Primary outcomes

1

Description
The severity of the pain
Timepoint
Before the intervention and the next two months
Method of measurement
VAS questionnair

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
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2

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Sponsors / Funding sources

1

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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
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Position
student
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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