Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of the Persian medicine product based on colchicum compared to placebo on pain and morning stiffness in patients with knee osteoarthritis: a triple-blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of a traditional medicine product based on colchicum on the clinical symptoms of patients with knee osteoarthritis

Design

A placebo-controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 70 patients. For randomization, patients are entered into the study by block randomization method in 35 blocks of size 2.

Settings and conduct

Patients referred to the rheumatology clinic of Rafsanjan University of Medical Sciences who are suffering from knee osteoarthritis and have the inclusion criteria are included in the study by block randomization method in 35 blocks of size 2. The researcher, the patients and the analyzer do not know the content of the packages and the study is triple blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 45 to 70 years with a diagnosis of knee osteoarthritis and pain between 3.5 and 7.5 cm based on the visual analogue scale. Non-inclusion criteria: pregnancy or breastfeeding, history of systemic diseases such as heart or renal failure and uncontrolled blood pressure, Routine use of oral analgesic, Intra-articular injection of corticosteroid drugs during the last six months

Intervention groups

The intervention group consists of 35 patients receiving two capsules daily of the product including colchicum rhizome, ashwagandha rhizome and mastic gum. The placebo control group includes 35 patients receiving two capsules of corn starch daily

Main outcome variables

Pain, morning stiffness, physical function, heel-to-thigh distance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230628058606N1**
Registration date: **2023-08-07, 1402/05/16**
Registration timing: **prospective**

Last update: **2023-08-07, 1402/05/16**
Update count: **0**

Registration date

2023-08-07, 1402/05/16

Registrant information

Name

Mahboobeh Raeiszadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 6167

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m.raeiszadeh@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of the Persian medicine product based on colchicum compared to placebo on pain and morning stiffness in patients with knee osteoarthritis: a triple-blind randomized clinical trial

Public title
The effect of the Persian medicine product based on colchicum on knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 45-75 years old Diagnosis of knee osteoarthritis based on the criteria of the American College of Rheumatology, which is confirmed by a rheumatology specialist. The presence of moderate knee pain within 24 hours based on linear-visual pain scale (VAS) between 3.5 and 7.5 cm. Completing the inform consent form
Exclusion criteria:
Pregnancy or breastfeeding Lack of physical and mental ability to answer questions Occurrence of debilitating disease during treatment History of allergy to herbal medicines use of alcohol or drug abuse History of systemic diseases such as heart failure, kidney failure and uncontrolled blood pressure Routine use of oral analgesic (except 500 mg oral acetaminophen daily) Consuming nutritional and medicinal supplements on a regular and daily basis Intra-articular injection of corticosteroid drugs during the last six months

Age
From **45 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are included in the study by block randomization in 35 blocks of size 2.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Capsules containing herbal medicine and placebo are placed completely similar packages after matching in terms of shape, smell and color and the packages are coded and provided to the researcher. The study is triple blind. Patients, researchers, and data analysts are blinded to capsule contents and codes. The person who codes the drugs has no role in patient selection and interpretation of results 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
Ethics committee of Kerman University of Medical Sciences
Street address
Faculty of Persian medicine; Kerman university of medical sciences; Haft-Bagh highway
City
Kerman
Province
Kerman
Postal code
7616913555

Approval date
2023-05-01, 1402/02/11

Ethics committee reference number
IR.KMU.REC.1402.018

Health conditions studied

1

Description of health condition studied
Osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Knee pain intensity

Timepoint
at the begining of intervention and 21 and 42 days after the intervention

Method of measurement
Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire, visual analogue scale (VAS) questionnaire

2

Description
morning stiffness of knee

Timepoint
at the begining of intervention and 21 and 42 days after the intervention

Method of measurement
Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire

3

Description
Physical performance
Timepoint
at the begining of intervention and 21 and 42 days after the intervention
Method of measurement
Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire

4

Description
Heel to thigh distance
Timepoint
at the begining of intervention and 21 and 42 days after the intervention
Method of measurement
Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 35 patients receiving capsules containing colchicum, ashwagandha and mustic gum twice a day for 42 days
Category
Treatment - Drugs

2

Description
Control group: 35 patients receiving capsules containing corn starch twice a day for 42 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology clinic of Rafsanjan University of Medical Sciences
Full name of responsible person
Mitra Abbasifard
Street address
Ali ibn Abi Talib Hospital; Ali ibn Abi Talib Square
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7717937555
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+98 34 3428 0185
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dr.mabbasifard@rums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abedin Iranpour
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Ebn-e-Sina St.,Jahad Blvd.,
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7619813159
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Email
abediniranpour@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Hossein Karegar-Borzi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine

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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
Not applicable
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