

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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

##### Email address

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 informed 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 analyst

**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 beginning 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 beginning 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 beginning 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 beginning 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 mistic 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

##### City

Rafsanjan

### Province

Kerman

### Postal code

7717937555

### Phone

+98 34 3428 0185

### Email

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

##### Street address

Ebn-e-Sina St.,Jahad Blvd.,

##### City

Kerman

##### Province

Kerman

##### Postal code

7619813159

##### Phone

+98 34 3226 3719

##### 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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kbhossein@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Hossein Karegar-Borzi

**Position**

Assistant professor

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

Kerman University of Medical Sciences

**Full name of responsible person**

Mahboobeh Raeiszadeh

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Fax****Email**

m.raeiszadeh@kmu.ac.ir

**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