

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Clinical effects of a herbal formulation in relieving inflammation and joint pains in patients with osteoarthritis

#### Protocol summary

##### Study aim

Investigating the clinical effects of a herbal formulation in relieving inflammation and joint pains in patients with osteoarthritis

##### Design

In this study, 60 patients with osteoarthritis that referred to the Imam Reza clinic will be selected based on the inclusion criteria and randomly divided into intervention and control groups. Each participant will be assigned a unique code.

##### Settings and conduct

This study, which will be carried out at the Imam Reza clinic in Kermanshah city, is double blinded and investigators and patients will be kept blinded to taking medication or placebo. At the beginning of the study, pain and joints stiffness in both groups will be recorded in a checklist

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Over 50 years old; No change in medication and treatment regimen in the last three months. Exclusion criteria: Pregnant women; women who intend to be pregnant; and lactating women; Addicted people (natural, synthetic or alcoholic drugs)

##### Intervention groups

The intervention group will receive the herbal medicine every night in the form of a topical cream in an approximate amount of two grams by rub on knee joint for one month. The control group, will receive the placebo every night in the form of a topical cream in an approximate amount of two grams by rub on knee joint for one month.

##### Main outcome variables

Joint pain; joints stiffness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131219015870N2**

Registration date: **2018-01-07, 1396/10/17**

Registration timing: **prospective**

Last update: **2018-01-07, 1396/10/17**

Update count: **0**

##### Registration date

2018-01-07, 1396/10/17

##### Registrant information

###### Name

Amir Kiani

###### Name of organization / entity

Kermanshah University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3427 6482

###### Email address

akiani@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

kermanshah University of Medical Sciences(KUMS)

##### Expected recruitment start date

2018-01-10, 1396/10/20

##### Expected recruitment end date

2018-06-10, 1397/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical effects of a herbal formulation in relieving inflammation and joint pains in patients with osteoarthritis

**Public title**

Clinical effects of a herbal formulation in relieving inflammation and joint pains

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Average age over 50 years During the last three months, the type and regimen of the medication and treatment used for the patient have not changed. Patients who have injected hyaluronic acid

**Exclusion criteria:**

Patients who have other diseases or use other medications Pregnant women, women who intend to have a pregnancy and breast-feeding women Addicted people (natural, synthetic or alcoholic drugs) Patients who will get another illness during treatment or be forced to use another drug

**Age**

From **50 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done using random number table.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the investigator and patients will be kept blind to taking medication or placebo

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2016-11-23, 1395/09/03

**Ethics committee reference number**

KUMS.REC.1395.505

**Health conditions studied****1****Description of health condition studied**

osteoarthritis

**ICD-10 code**

M19.9

**ICD-10 code description**

Arthrosis, unspecified

**Primary outcomes****1****Description**

joint pain

**Timepoint**

At the beginning of the study and the end of the study (one month later)

**Method of measurement**

Using the The Western Ontario and McMaster Universities Osteoarthritis questionnaire (WOMAC)

**2****Description**

Dryness of the joint

**Timepoint**

At the beginning of the study and the end of the study (one month later)

**Method of measurement**

Using the The Western Ontario and McMaster Universities Osteoarthritis questionnaire (WOMAC)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The intervention group will receive the herbal medicine every night in the form of a topical cream in an approximate amount of two grams by rub on knee joint for one month

**Category**

Treatment - Drugs

## 2

### Description

The control group, will receive the placebo every night in the form of a topical cream in an approximate amount of two grams by rub on knee joint for one month.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

KUMS

##### Full name of responsible person

Amir kiani

##### Street address

Emam Reza Hospital, Parastar Boulevard

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3427 6306

##### Email

akiani@kums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Farid Najafi

##### Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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##### Province

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+98 83 3836 0014

##### Email

fnajafi@kums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice chancellor for research of Kermanshah University of

Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Private

##### 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

Elham Choolaki

##### Position

Medicine student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

##### Street address

School of Medicine, parastar boulevard

##### City

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##### Province

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##### Phone

+98 83 3427 4618

##### Fax

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elhamchoolaki@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Amir Kiani

##### Position

Faculty Member of Medical University

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Toxicology

##### Street address

Shahid Shiroodi Blvd., Faculty of Pharmacy

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##### Province

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## Person responsible for updating data

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Kermanshah University of Medical Sciences

**Full name of responsible person**

Elham Choolaki

**Position**

Medicine student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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elhamchoolaki@gmail.com

**Web page address**

## Sharing plan

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

Yes - There is 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**

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**

Not applicable

**Title and more details about the data/document**

The main outcomes of the study will be shared.

**When the data will become available and for how long**

6 months

**To whom data/document is available**

If requested, results will be made available to other academic researchers

**Under which criteria data/document could be used**

En Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

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

En In a 15-day period, the documents will be sent e-mail

**Comments**