

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A clinical trial for determination of the effect of Curcumin ointment on knee pain and quality of life in older adults with osteoarthritis

#### Protocol summary

##### Study aim

Evaluation of the effect of Curcumin ointment on knee pain and quality of life in older adults with osteoarthritis

##### Design

A single-blind randomized controlled trial will be conducted on two groups of 36 patients.

##### Settings and conduct

Among the older adults referring to the physician's office, 72 eligible ones will be recruited into two groups of 36. A Visual Analog Scale and the OAKHQOL quality of life questionnaire will be used to assess the severity of knee pain and quality of life at the beginning of the study and at the end of the 4th and the 6th weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 60 years and over, Lack of a known allergy to the herbs of Zingiberaceae family, Lack of known cognitive impairments, Being conscious and able to answer the questionnaire, Having a medical diagnosis of knee osteoarthritis, Willingness to participate and signing the informed consent form.

Exclusion criteria: Occurrence of any allergic reactions to Curcumin ointment, Discontinuing the ointment before the study end, A patient's death or decision to withdraw from the study, Hospitalization and/or moving to other cities.

##### Intervention groups

1.5 mL of 5% Curcumin ointment will be used in the intervention group twice a day, for six weeks. Vaseline ointment will be used for patients in the control group with a schedule similar to the intervention group.

##### Main outcome variables

The severity of knee pain and quality of life

#### General information

##### Reason for update

##### Acronym

ECONPQOL

##### IRCT registration information

IRCT registration number: **IRCT20100403003618N6**

Registration date: **2019-03-08, 1397/12/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-08, 1397/12/17**

Update count: **0**

##### Registration date

2019-03-08, 1397/12/17

##### Registrant information

###### Name

Mohsen Adib-Hajbaghery

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36155540021

###### Email address

adibhajbagheri\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2019-06-22, 1398/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial for determination of the effect of Curcumin ointment on knee pain and quality of life in older adults with osteoarthritis

## Public title

The effect of Curcumin ointment on knee pain and quality of life in older adults with osteoarthritis

## Purpose

Other

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of 60 years and over. Lack of a known allergy to herbs of the Zingiberaceae family. Lack of a known cognitive impairment (in the assessment of time, place, and person). Being fully conscious and able to answer the questionnaire items. Having a medical diagnosis of knee osteoarthritis. Willingness to participate in the study and signing the informed consent form.

### Exclusion criteria:

Appearance of systemic or dermatological allergic reactions to Curcumin ointment during the study. Discontinuing the prescribed ointment before the end of the intervention (at least for three consecutive days). A patient's decision to withdraw from the study. Death of the patient. Hospitalization and/or moving to other cities.

## Age

From **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **72**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Permuted blocked randomization will be used through an online randomizer, to randomly assign 72 older adults with knee pain into 12 six-subject blocks and create two groups of 36 subjects.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Patients will be unaware of the type of treatment they receive, and the drugs of the two groups will be prepared in the same containers

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

#### Street address

Ravand Street, Kashan

#### City

Kashan

#### Province

Isfahan

#### Postal code

87159-81151

#### Approval date

2019-01-14, 1397/10/24

#### Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1397.049

## Health conditions studied

### 1

#### Description of health condition studied

Knee pain and quality of life

#### ICD-10 code

M15-M19

#### ICD-10 code description

osteoarthritis

## Primary outcomes

### 1

#### Description

Knee pain

#### Timepoint

Before the intervention, four weeks after the intervention, six weeks after the intervention.

#### Method of measurement

The score of a Visual Analog Scale for knee pain.

## Secondary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Before the intervention, four weeks after the intervention, six weeks after the intervention.

#### Method of measurement

The score of Osteoarthritis Knee and Hip Quality of Life Questionnaire.

## Intervention groups

### 1

#### Description

The intervention group: 1.5 mL of 5% Curcumin ointment will be prescribed twice a day (once in the morning and once at night before bedtime), for six weeks.

#### Category

Treatment - Drugs

## 2

### Description

The control group: 1.5 mL of Vaseline ointment will be prescribed twice a day (once in the morning and once at night before bedtime), for six weeks.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The office of the physician who cooperate in the study.

##### Full name of responsible person

Dr. Alireza Soleimani

##### Street address

The Dey physicians' complex, Ziarati street, Kashan, Iran.

##### City

Kashan

##### Province

Isfahan

##### Postal code

87147-98941

##### Phone

+98 31 5534 0508

##### Email

jamali\_neda@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Dr. Hamid Reza Banafsheh

##### Street address

Ravand Street, Kashan

##### City

Kashan

##### Province

Isfahan

##### Postal code

87159-81151

##### Phone

+98 31 5555 4299

##### Email

reaserch@kaums.ac.ir

##### Grant name

##### Grant code / Reference number

97151

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

Yes

##### Title of funding source

Kashan 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

Kashan University of Medical Sciences

##### Full name of responsible person

Neda Jamali

##### Position

Master of Science Student in Geriatric Nursing

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

The 16th Tohid alley, 22 Bahman street, Kashan, Iran.

##### City

Kashan

##### Province

Isfahan

##### Postal code

87147-98941

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Dr. Mohsen Adib-Hajbaghery

##### Position

PhD in Nursing Education

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Ravand Street, Kashan

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

Kashan University of Medical Sciences

**Full name of responsible person**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The participants' data will keep confidential.

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

No - There is not 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