Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 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)

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+98 36155540021

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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
Isfehan
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.
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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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position
Master of Science Student in Geriatric Nursing

Latest degree
Master

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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