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

Purpose

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
- Permuter 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
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

Recruitment center

Name of recruitment center
The office of the physician who cooperate in the study.

Full name of responsible person
Dr. Alireza Soleimani

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

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Sponsors / Funding sources

Sponsor

Name of organization / entity
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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

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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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