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

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
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
Phone
+98 31 5534 0508
Email
jamali_neda@yahoo.com

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
City
Kashan
Province
Isfahan
Postal code
87159-81151
Phone
+98 31 5554 0021
Email  
adib1344@yahoo.com

**Person responsible for updating data**

**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
- **Phone**
  +98 31 5534 0508

Email  
jamali_neda@yahoo.com

**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