Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of hydroalcoholic extract of olive leaf on osteoarthritis of the knee and daily functioning of the elderly

Protocol summary

Study aim
Determining the effect of olive leaf extract on the physical function of the elderly with knee osteoarthritis.

Design
Clinical trial with intervention group, with factorial groups, phase 2 stratified random block on 120 patients. Random number table is used for randomization.

Settings and conduct
After referring the elderly to the orthopedic clinic and confirming the diagnosis of osteoarthritis by an orthopedic specialist, explaining the objectives of the research to the elderly, obtaining informed consent, dividing into four groups of 30 people, stratified random blocking and pain assessment using visual analog scale.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Have Osteoarthritis Grade 1-3 Based on American College of Rheumatology Classification Criteria Having moderate pain according to visual analog criteria (4-7) Exclusion criteria: Creating acute medical conditions The death of the elderly at the time of study

Intervention groups
Group 1: Receive topical olive leaf extract ointment in the form of 15 ml in the tibiofemoral area three times a day, along with routine treatment with acetaminophen 500 mg three times a day Group2: Take capsules containing 60 mg of olive leaf extract orally with a meal three times a day for eight weeks and with routine treatment with acetaminophen 500 mg three times a day. Group3: Topical olive leaf extract ointment 15 ml oral capsules containing 60 mg of olive leaf extract three times a day with routine treatment. Group 4: Receive routine treatment.

Main outcome variables
Proper physical function, pain relief,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170514033961N7**
Registration date: **2021-01-23, 1399/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-23, 1399/11/04**
Update count: **0**

Registration date
2021-01-23, 1399/11/04

Registrant information

Name
Mandana Saki

Name of organization / entity
Lorestan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 66 3331 6465

Email address
m.saki@modares.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-03, 1399/10/14

Expected recruitment end date
2021-04-03, 1400/01/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of hydroalcoholic extract of olive leaf on osteoarthritis of the knee and daily functioning of the elderly

Public title
The effect of olive extract on arthrosis of the knee
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The individual's desire to participate in the study Being 60-80 years old Diagnosis of primary osteoarthritis of the knee Participating in the study based on the diagnosis of an orthopedic specialist (based on the description of clinical symptoms, physical examination, radiographic criteria and diagnostic properties related to the disease) Have Osteoarthritis Grade 1-3 Based on American College of Rheumatology Classification Criteria Having moderate pain according to visual analog criteria (4-7) No dependence on others in performing daily activitiesFailure to perform physiotherapy and surgery in the last 12 months No intra-articular injection of steroids in the last 6 months Having a body mass index of less than 30 Have a performance score above 34 No neurological diseases associated with movement and balance disorders
Exclusion criteria:
Creating acute medical conditions The death of the elderly at the time of study Reluctance to continue participating in the study Sensitivity to olives Existence of cognitive disorders Secondary osteoarthritis in rheumatologydiseases (such as rheumatoid arthritis, gout, infectious arthritis, metabolic arthritis, traumatic arthritis)
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples included in the study are placed in four groups using random stratified blocking method. The method of allocating 120 eligible samples in 4 groups of 30 is as follows, taking into account the sex class (male and female) and in A total of 4 floors are formed. Within each class, the method of 4 random blocks is used to assign patients to the four groups studied. To do this, first write the list of blocks and assign numbers to them (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)) then using A table of random numbers will be assigned to them at random, and finally a list of treatment assignments will be formed based on a sequence of letters A and B.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Lorestan University of Medical Science
Street address
Vice Chancellor for Research and Technology, Lorestan, Khorramabad, Road, Pardis University Complex University of Medical Sciences,
City
KHorramabd
Province
Lorestan
Postal code
6813833946
Approval date
2021-01-17, 1399/10/28
Ethics committee reference number
IR.LUMS.REC.1399.265

Health conditions studied

1

Description of health condition studied
osteoarthrit
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Knee pain score
Timepoint
The beginning of the study, the second, fourth, sixth, eighth week
Method of measurement
Visual Analog Scale,

2

Description
Joint dryness score
Timepoint
The beginning of the study, the second, fourth, sixth, eighth week
Method of measurement
Osteoarthritis Index of West Ontario University and

McMaster

3

Description
Psychological performance score
Timepoint
The beginning of the study, the second, fourth, sixth, eighth week
Method of measurement
Osteoarthritis Index of West Ontario University and McMaster

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: For intervention in this group, high quality olive leaf extract ointment of coronaci species prepared by Danakasia company is provided to the research samples and they will be trained to use 15 ml of it topically in the tibiofemoral area three times a day for eight weeks. Also continue their routine treatment during the intervention period, which includes taking acetaminophen 500 mg tablets every eight hours.Intervention group 2: Capsules containing 60 mg of high quality olive leaf extract powder of Cronaci species prepared by Danacasia company will be provided to the research samples and they will be trained to take it orally with each meal three times a day for eight weeks and also during the course. Continue your routine treatment intervention, which includes taking acetaminophen 500 mg tablets every eight hours.Intervention group 3: Capsules containing high quality olive leaf extract along with ointment containing olive leaf extract prepared by Danakasiarad company are provided with research samples and they will be trained to take them orally with food every day for eight weeks and three times a day, respectively. Topically in the tibiofemoral area and also during the intervention period, continue their routine treatment, which includes taking acetaminophen 500 mg tablets every eight hours. Intervention group 4: Take routine treatment, including taking acetaminophen 500 mg tablets every eight hours, and do not use any other medicine to relieve this drug.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthopedic office
Full name of responsible person
mandana saki
Street address
No. 18, Rose Alley,Enghelab St.,Khorramabad, Lorestan
City
KHorramabad
Province
Lorestan
Postal code
6819834525
Phone
+98 66 3331 6465
Fax
+98 66 3312 0140
Email
mandana-saki@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Flahi Ebrahim
Street address
Vice Chancellor for Research and TechnologyUniversity Complex, Lorestan University of Medical SciencesPardis,Khorramabad, Khorramabad-Borujerd Road,Lorestan
City
khorram abad
Province
Lorestan
Postal code
6861915857
Phone
+98 66 3312 0172
Fax
+98 66 3312 0140
Email
edu-res@lums.ac.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
saki mandana

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
No. 18, Rose Alley, Enghelab St., Lorestan, Khorramabad

City
Khorram abad

Province
Lorestan

Postal code
6819834525

Phone
+98 66 3331 6465

Fax
+98 66 3312 0140

Email
mandana-saki@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
mandana saki

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
No. 18, Rose Alley,Enghelab St.Khorramabad, Lorestan,

City
KHorram abad

Province
Lorestan

Postal code
6819834525

Phone
+98 66 3331 6465

Fax
+98 66 3312 0140

Email
mandana-saki@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
mandana saki

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
No. 18, Rose Alley,Enghelab St.Khorramabad, Lorestan

City
KHorram abad

Province
Lorestan

Postal code
6819834525

Phone
+98 66 3331 6465

Fax
+98 66 3312 0140

Email
mandana-saki@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data is released after unidentifiable individuals in the form of original message information.

When the data will become available and for how long
The access period will start from 2021

To whom data/document is available
All researchers, lecturers, medical students can receive the published article from the relevant journal.

Under which criteria data/document could be used
Unidentifiable data will be made available to health researchers for the study of meta-analysis.

From where data/document is obtainable
end email to Mandanasaki.m.saki@modares.ac.ir

What processes are involved for a request to access data/document
After sending the documents by the applicant researcher

via email, the data will be sent two weeks later.

Comments