Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Topical effect of cicer arientinumr extract on some clinical signs of knee osteoarthritis: a randomized and double blind clinical trial

Protocol summary

Study aim
Topical effect of cicer arientinumr extract on some clinical signs of knee osteoarthritis: a randomized and double blind clinical trial

Design
a double blind clinical trial

Settings and conduct
The present study is done in the second half of 1396 on patients with osteoarthritis referring to Rheumatology clinic of Rafsanjan. The amount of pain, morning stiffness, range of motion and function of patients in all three interventional groups at the beginning and the end of the study, will be evaluated with the linear-visual pain scale and the WOMAC scale. cicer arientinum is prepared by a pharmaceutical specialist. data will analyzed by spss v19

Participants/Inclusion and exclusion criteria
1. inclusion criteria: Age 50 - 70 years, Diagnosis of knee osteoarthritis according to the American College of Rheumatology criteria, which approved by Rheumatologist., The presence of moderate knee pain within 24 hours based on the linear-visual pain scale (VAS) between 4 to 7 cm 2. exclusion criteria: Patients with inflammatory diseases (such as lupus, rheumatoid arthritis, history of brucellosis, etc.), cancer or severe illness, Symptoms or history of liver or kidney failure, Corton consumption in the last 4 weeks, Corton injection over the past 6 months, Fever, Consumption of herbal medicine continuously, Sensitivity to cicer arientinum , Unwillingness to continue participating in the study, Failure to observe the study protocol, See any complications caused by cicer arientinumr , Use of food and pharmaceutical supplements, daily painkiller consumption, Very advanced disease.

Intervention groups
Patients are divided into three groups A, B, and C . In group A, the pyroxycam gel, in group B cicer arientinum extraction and in group C paraffin for placebo will used topically.

Main outcome variables
Linear-visual pain scale and WOMAC scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181030041500N1**
Registration date: **2019-04-30, 1398/02/10**
Registration timing: **retrospective**

Last update: **2019-04-30, 1398/02/10**
Update count: **0**

Registration date
2019-04-30, 1398/02/10

Registrant information

Name
pooya saeed askari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3281 2464

Email address
p.saeedaskari@rums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2017-12-21, 1396/09/30

Actual recruitment start date
2017-09-23, 1396/07/01

Actual recruitment end date
2018-01-20, 1396/10/30

Trial completion date
2018-04-20, 1397/01/31

Scientific title
Topical effect of cicer arientinumr extract on some clinical signs of knee osteoarthritis: a randomized and double blind clinical trial

Public title
Topical effect of cicer arientinumr extract on some clinical signs of knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of knee osteoarthritis according to the American College of Rheumatology criteria, which approved by Rheumatologist The presence of moderate knee pain within 24 hours based on the linear-visual pain scale (VAS) between 4 to 7 cm 2 Age between 50 to 70 years old

Exclusion criteria:
Patients with inflammatory diseases (such as lupus, rheumatoid arthritis, history of brucellosis, etc.), cancer or severe illness Symptoms or history of liver or kidney failure consumption Corton in the last 4 weeks Corton injection over the past 6 months Fever Consumption of herbal medicine continuously Sensitivity to cicer arientinum Unwillingness to continue participating in the study Failure to observe the study protocol See any complications caused by cicer arientinumr Use of food and pharmaceutical supplements daily painkiller consumption Very advanced disease

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **75**
Actual sample size reached: **75**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
for double blind study creating, before the study begins, the drugs will be enclosed by someone (not researcher) in the same packages and encoded in A, B, and C. Rheumatologist prescribed as either A or B or C which drug delivery is done by another person. Assessment of clinical symptoms is done by a resident who is not aware of the type of drug consumption.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Rafsanjan university of medical sciences

Street address
Ali-ebb Abitaleb Square, Ali-Ebn Abitakeb Hospital

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2018-08-18, 1397/05/27

Ethics committee reference number
IR.RUMS.REC.1397.092

Health conditions studied

1

Description of health condition studied
osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
knee pain level in Visual Analogue Scale

Timepoint
At the beginning and the end of the study (three months after the beginning of the study)

Method of measurement
Visual Analogue Scale – VAS

2

Description
Western Ontario and Mc Master (womac) degree

Timepoint
At the beginning and the end of the study (three months after the beginning of the study)

Method of measurement
Western Ontario and Mc Master (womac) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group B: topically received cicer arientinumr extraction twice a day for three months. Patients in all three groups can use oral drugs to relieve pain in the same way.
Category
Treatment - Drugs

2

Description
Control group: Group C: topically received Paraffin (placebo) twice a day for three months for comparing the effects of other groups. Patients in all three groups can use oral drugs to relieve pain in the same way.
Category
Treatment - Drugs

3

Description
Intervention group: Group A: Topically received piroxicam gel for twice a day for 3 months. Patients in all three groups can use oral drugs to relieve pain in the same way.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology Clinic of Rafsanjan University of Medical Sciences
Full name of responsible person
Dr. Mitra Abbasi Fard
Street address
Ali-ebn AbiTaleb Hospital, Ali-ebn AbiTaleb Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Dr. Ali Shamsizadeh
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Pooya Seaad Askari
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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
Undecided - It is not yet known if there will be 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