Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Effect of topical application of Eugenia caryophylata extract compared with diclofenac and placebo on primary knee osteoarthritis

Protocol summary

Summary

In this clinical trial, 120 patients with osteoarthritis of the knee according to VAS, will be selected and randomly divided into 3 groups of 35 persons. The first group will receive one mg topical diclofenac 1% 3 times daily, second group will receive 10% of Clove extract ointment 3 times daily , the third group will receive placebo topical 1 mg 3 times daily. For all three groups questionnaire (WOMAC) in four sets, which includes baseline, one week, three weeks and four weeks after treatment will be completed. In the questionnaire, general pain, knee pain, morning stiffness, stiffness and physical activity throughout the day will be assessed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501056480N8**
Registration date: **2015-01-27, 1393/11/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-27, 1393/11/07

Registrant information

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Name of organization / entity
Shahrekord University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Science

Expected recruitment start date

2015-01-15, 1393/10/25

Expected recruitment end date

2015-04-11, 1394/01/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical application of Eugenia caryophylata extract compared with diclofenac and placebo on primary knee osteoarthritis

Public title

Effect of Eugenia caryophylata extract on primary knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : having 30 years old , maximum 60 years, knee osteoarthritis proven by clinical symptoms, examination and diagnosis criteria of this disease, which despite the usual care is not relieved for 3 months. Exclusion criteria: presence of severe concomitant diseases such as metabolic and gastrointestinal diseases, fluctuating doses of drugs during the study, severe infection, allergy to clove extract, pregnancy, lactation.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahrekord University of Medical Sciense
Street address
Vice Chancellor for research of Shahrekord University of Medical Sciences, Kashani Boulevard
City
Shahrekord
Postal code
Approval date
2013-02-01, 1391/11/13
Ethics committee reference number
91-12-20

Health conditions studied

1

Description of health condition studied
primary knee osteoarthritis
ICD-10 code
M15.0
ICD-10 code description
Primary generalized (osteo)arthrosis

Primary outcomes

1

Description
general pain
Timepoint
baseline, one week, three weeks and four weeks after treatment
Method of measurement
questionnaire (WOMAC)

2

Description
stiffness
Timepoint
baseline, one week, three weeks and four weeks after treatment
Method of measurement
questionnaire (WOMAC)

3

Description
physical activity
Timepoint
baseline, one week, three weeks and four weeks after treatment
Method of measurement
questionnaire (WOMAC)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group received the amount of 1 mg of Clove extract ointment 10%3 times daily.
Category
Treatment - Drugs

2

Description
Intervention Group received 1 mg of topical diclofenac 1% 3 times daily .
Category
Treatment - Drugs

3

Description
Control group received1 mg of placepo ointment 3 times daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Educational Clinic of Shahrekord University of Medical Science
Full name of responsible person
Dr. Mortaza Dehghan
Street address
Educational Clinic of Shahrekord University of Medical Science, Shariati Blvd.

City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellery for Research and Technology,Shahrekord University of Medical Sciences
Full name of responsible person
Dr Mahmoud Mobasheri
Street address
Vice Chancellor for research of Shahrekord University of Medical Sciences, Kashani Boulevard
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellery for Research and Technology,Shahrekord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty