

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of topical application of *Eugenia caryophyllata* 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

Name

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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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+98 38 1334 9509

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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 caryophyllata* extract compared with diclofenac and placebo on primary knee osteoarthritis

Public title

Effect of *Eugenia caryophyllata* 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 Science

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 received 1 mg of placebo 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
Dr Morteza Dehghan

Position
Assistant Profrrsor

Other areas of specialty/work

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Person responsible for scientific inquiries

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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