

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of effectiveness of topical chamomile flower extract in sesame oil with Diclofenac gel and placebo on clinical symptoms in patients with mild to moderate knee osteoarthritis

Protocol summary

Summary

This is a Double-Blinded randomized clinical study to compare the effects of chamomile flower extract in sesame oil with Diclofenac gel and placebo (liquid paraffin) on patients with clinical symptoms of knee osteoarthritis. 99 patients after taking signed informed consent, according to American College of Rheumatology classification criteria for osteoarthritis and Kellegren-Lawrence system of classification by the physiatrist, in the age range 65-38 years are accepted. They will allocate to three arms using block randomization. 30 acetaminophen 500 milligrams tablets also given to the patients to use for pain relief if needed. Drugs will be encoding and without the name, three times a day for 3 weeks will prescribe to intervention groups. Patients at the beginning and weekly from the beginning of the study will be evaluated by the WOMAC questionnaire until the third week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015013120885N1**
Registration date: **2015-03-10, 1393/12/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-10, 1393/12/19

Registrant information

Name

Ruhollah Shoara

Name of organization / entity

Shiraz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-02-09, 1393/11/20

Expected recruitment end date

2015-03-19, 1393/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of topical chamomile flower extract in sesame oil with Diclofenac gel and placebo on clinical symptoms in patients with mild to moderate knee osteoarthritis

Public title

The evaluation of effectiveness of topical chamomile flower extract in sesame oil on clinical symptoms in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the age between 38-65 years; patient's written informed consent for inclusion; recognition of osteoarthritis by the physiatrist according to American college of rheumatology classification criteria;

recognition of grade I to III by the physiatrist osteoarthritis according to Kellegren-Lawrence system of classification. Exclusion Criteria: those who need more than 2 grams of acetaminophen per day; those who need to use other oral or intravenous analgesic; unwillingness to continue to participate in the study; sensitivity to study drugs; patients with other bone joint disorders like rheumatoid arthritis, gout, pseudo gout, infected arthritis, metabolic arthritis, traumatic arthritis, joint replacement, fibromyalgia, non-motor dysfunction related to hip or knee (radiculopathy and neuropathy); concomitant use of glucosamine and chondroitin sulfate; knee corticosteroid injection in the past 3 months; other articular corticosteroid injection in the past 1 month; taking muscle relaxant drugs; pregnancy; oral and local use of corticosteroid in 14 past days; muscle corticosteroid injection in the past 1 month; alcohol addicted; drug abuse; skin diseases in knee; patients with active renal, liver and peptic ulcer diseases; disability to cooperate in filling the forms (cognitive or language disorder).

Age

From **38 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **99**

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**

Shiraz University of Medical Sciences

Street address

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Street.

City

Shiraz

Postal code**Approval date**

2015-02-08, 1393/11/19

Ethics committee reference number

CT-9376-7366

Health conditions studied**1****Description of health condition studied**

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Gonarthrosis

Primary outcomes**1****Description**

Pain

Timepoint

At the beginning of intervention and after 1 week, 2 weeks and 3 weeks after the beginning of intervention

Method of measurement

WOMAC questionnaire

2**Description**

Joint stiffness

Timepoint

At the beginning of intervention and after 1 week, 2 weeks and 3 weeks after the beginning of intervention

Method of measurement

WOMAC questionnaire

3**Description**

Function

Timepoint

At the beginning of intervention and after 1 week, 2 weeks and 3 weeks after the beginning of intervention

Method of measurement

WOMAC questionnaire

4**Description**

The need for acetaminophen 500 milligrams tablets

Timepoint

1 week, 2 weeks and 3 weeks after the beginning of intervention

Method of measurement

Asking from patients

Secondary outcomes

empty

Intervention groups

1

Description

Chamomile flower extract in sesame oil, three times a day, topically on the more painful knee

Category

Treatment - Drugs

2

Description

Diclofenac 1% topical gel, three times a day on the more painful knee

Category

Treatment - Drugs

3

Description

Liquid Paraffin, topically, three times a day on the more painful knee

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahhari Clinic

Full name of responsible person

Dr. Ruhollah Shoara

Street address

Iranian Traditional Medicine College, Medicine Faculty, Imam Hossein Square, Zand Street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyyed Basir Hashemi

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Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Street.

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ruhollah Shoara

Position

The Assistant of Traditional Medicine

Other areas of specialty/work

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Fax**Email****Web page address****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