Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

Iran (Islamic Republic of)

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+98 71 3627 0244

Email address

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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
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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
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Full name of responsible person
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Person responsible for scientific inquiries

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Person responsible for updating data

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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