

# 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

Iran (Islamic Republic of)

##### Phone

+98 71 3627 0244

##### Email address

shoara@sums.ac.ir

##### 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

##### Street address

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

##### Street address

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

##### City

Shiraz

##### Postal code

##### Phone

+98 71 3230 5886

##### Fax

##### Email

shoara@sums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Alireza Ashraf

##### Position

Professor of Physical Medicine and Rehabilitation

##### Other areas of specialty/work

##### Street address

Shiraz University of Medical Sciences - Department of Physical Medicine and Rehabilitation

##### City

Shiraz

##### Postal code

##### Phone

+98 71 3231 9040

##### Fax

##### Email

Ashrafa@sums.ac.ir

##### Web page address

## Person responsible for updating data

#### 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****Street address**

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

**City**

Shiraz

**Postal code****Phone**

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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*