

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of the topical application of chamomile oil on rheumatoid arthritis knee pain in older women

#### Protocol summary

##### Study aim

Determination of the effect of the topical application of chamomile oil on rheumatoid arthritis knee pain in older women

##### Design

The present study is a non-randomized clinical trial with placebo group (semi-experimental) with parallel and one-way blind groups.

##### Settings and conduct

The two educational centers of Firouzgar and Hazrat-e Rasool, affiliated to Iran University of Medical Sciences, are considered as research environments. All elderly women (aged 60-75) with knee rheumatoid arthritis constitute the community of research.

##### Participants/Inclusion and exclusion criteria

Older women aged 60-75; having rheumatoid arthritis knee disease; not having concurrent (non-pharmacological) treatment for pain associated with rheumatoid arthritis; lack of cognitive impairment of the elderly by the AMT scale; absence of brittleness of the skin; having a high VAS score.

##### Intervention groups

The present study is a clinical trial (quasi-experimental) with two experimental and placebo groups. For the test group, oil is treated by a researcher and a sample. As much as 1.5 cc of chamomile oil is used twice a day and 6 hours apart, the first time is used by the researcher and secondly by the specimen. The same amount of liquid paraffin is used in the placebo group.

##### Main outcome variables

Regarding the multiplicity of drugs in the elderly and its complications, the use of complementary and alternative therapies for the improvement of pain in elderly patients with rheumatoid arthritis can be considered as valuable and it is possible to use this low cost and uncomplicated method in this group of elderly people.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180809040749N1**

Registration date: **2018-09-08, 1397/06/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-08, 1397/06/17**

Update count: **0**

##### Registration date

2018-09-08, 1397/06/17

##### Registrant information

##### Name

Mina Janalizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6663 9900

##### Email address

janalizadeh.m@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-18, 1397/05/27

##### Expected recruitment end date

2018-09-19, 1397/06/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of the topical application of chamomile oil on rheumatoid arthritis knee pain in older women

**Public title**

The effect of the topical application of chamomile oil on pain

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Older women aged 60-75 Having a knee rheumatoid arthritis disease (according to medical records) Having a VAS score above 3

**Exclusion criteria:**

Elderly cognitive disorder by AMT scale Concomitant (non-pharmacological) treatment for pain associated with rheumatoid arthritis, such as massage therapy, acupuncture, kaeropraktika, yoga, ayurveda, traditional Chinese medicine Skin brittleness due to diseases such as liver dysfunctions, etc. (based on records of medical records).

**Age**

From **60 years** old to **75 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **96**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants in the test and placebo groups are selected from two separate hospitals, plus they receive oils in similar cans.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

**Street address**

Unit 6, No 9, Salabat 8th Alley, Salabat Street, Velayat Ave, Farzan Town, Kalhor Blvd, Shahre ghods,

Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

3751374827

**Approval date**

2017-06-12, 1396/03/22

**Ethics committee reference number**

IR.IUMS.REC.1396.9411580002.

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

Rheumatoid Arthritis

**ICD-10 code**

M00-M99

**ICD-10 code description**

XIII Diseases of the musculoskeletal system and connective tissue

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

Intensity of pain

**Timepoint**

Before intervention, immediately after intervention, 2 hours after intervention

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: For the test group, oil is treated by a researcher and a sample. As soon as 1.5 cc of chamomile oil is applied twice a day for 6 hours, first by the researcher and secondly by the specimen and with the help of a dropper on the affected joint skin and around it, and slowly spread over until oil is on The skin will disappear so that the friction between the hands and skin of the patient is minimized to prevent heat generation. Non-fat chamomile oil has been produced by Shafa Kordestan Company under the supervision of Iran's Herbal Medicine Company under license No. 10335/41 of the Ministry of Health and Medical Education. Specified amount of oil is provided in small plastic cans that can be easily opened and closed.

**Category**

Treatment - Drugs

## 2

### Description

Control group: In the placebo group, a similar amount of 1.5 cc of liquid sanitary paraffin is used.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul-e-Akram Medical Education Complex

##### Full name of responsible person

Hassan Amiri

##### Street address

Rasoul-e-Akram Medical Education Complex,  
Mansouri St, Niayesh St, Sattarkhan, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۴۵۶۱۳۱۳۱

##### Phone

+98 21 6651 4001

##### Email

mina.janalizadeh@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Firoozgar Medical Education Complex

##### Full name of responsible person

Farhad Zamani

##### Street address

Firoozgar Hospital, Beh Afarin St, Karim Khan St, Vali-e-Asr Square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۵۹۳۷۴۷۸۱۱

##### Phone

+98 21 8214 1600

##### Email

h\_firoozgar@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Kazem Malakooti

##### Street address

Iran University of Medical Sciences, Hemat Highway  
next to Milad Tower, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۴۹۶۱۴۵۳۵

##### Phone

+98 21 8670 1021

##### Email

PR@iums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Iran University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Mina Janalizadeh

##### Position

Masters student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Unit 6, No. 9, 4th Alley, Salabat Av, Velayat Av,  
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##### Email

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## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available