

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effects of alendronate on the function and pain in patients with knee osteoarthritis referred to Rheumatology Clinic

#### Protocol summary

##### Study aim

Determining the effects of alendronate on the function and pain in patients with knee osteoarthritis referred to Rafsanjan Rheumatology Clinic in 2021

##### Design

A clinical trial with a control group, with parallel groups, randomized, phase 3 on 80 patients, for randomization a random number table was used.

##### Settings and conduct

Clinical trial will be performed in 2023 on osteoarthritis patients referred to the Rheumatology Clinic of Rafsanjan. Patients will be evaluated at the beginning of the study and one and two months after the intervention using the Visual Analogue Scale (VAS) and the WOMAC index.

##### Participants/Inclusion and exclusion criteria

Age 45-70 years, the diagnosis of osteoarthritis is based on the criteria of the American College of Rheumatology, which is confirmed by a rheumatology specialist.  
Exclusion: Patients suffering from inflammatory diseases  
Cancer with serious diseases of liver or kidney failure,  
Oral corticosteroid use in the last 4 weeks, Cortisone injection in the last 6 months, Fever, Consuming medicinal plants, Unwillingness to continue participating in the study, Consuming painkillers on a regular daily basis.

##### Intervention groups

Participants will be divided into two groups: Group 1 (40 people) using using alendronate. Group 2 (40 people) placebo.

##### Main outcome variables

Pain and status of osteoarthritis range of motion, morning dryness and physical function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180811040759N5**

Registration date: **2023-10-24, 1402/08/02**

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

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

##### Registration date

2023-10-24, 1402/08/02

##### Registrant information

###### Name

Mitra Abbasifard

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3428 0040

###### Email address

dr.mabbasifard@rums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-07, 1402/07/15

##### Expected recruitment end date

2023-11-06, 1402/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of alendronate on the function and pain in patients with knee osteoarthritis referred to Rheumatology Clinic

##### Public title

The effects of alendronate on the function and pain in patients with knee osteoarthritis referred to Rheumatology Clinic

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Age 45-70 years The diagnosis of osteoarthritis of the knee according to the criteria of the American College of Rheumatology, which is confirmed by a specialist in hematology

##### **Exclusion criteria:**

Patients suffering from inflammatory diseases (such as lupus, rheumatoid arthritis, history of brucellosis, etc.)  
Cancer with serious diseases  
Symptoms with a history of liver or kidney failure  
Oral corticosteroid use in the last 4 weeks  
Cortisone injection in the last 6 months  
Fever  
Consuming medicinal plants continuously  
Unwillingness to continue participating in the study  
Use of dietary and medicinal supplements  
Consuming painkillers on a regular daily basis and very advanced disease

#### **Age**

From **45 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Simple randomization method. Unit: individual, simple randomization tool: first, stewartritis patients were randomly selected from among the clients to the clinic according to clinical evidence and randomly divided into two groups: control group and alendronate group without regard to gender. It should be noted that there were 40 people in the control group and 40 people in the Alendronite group.people.

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Rafsanjan University of Medical

Sciences

#### **Street address**

Ali ibn Abi Talib Square, Ali ibn Abi Talib Hospital

#### **City**

Rafsanjan

#### **Province**

Kerman

#### **Postal code**

7717933777

#### **Approval date**

2021-04-05, 1400/01/16

#### **Ethics committee reference number**

IR.RUMS.REC.1400.161

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Osteoarthritis

##### **ICD-10 code**

M17

##### **ICD-10 code description**

Osteoarthritis of knee

### **Primary outcomes**

#### **1**

##### **Description**

Knee pain intensity

##### **Timepoint**

At the beginning and the end of the study (two months after the beginning of the study)

##### **Method of measurement**

Visual Analogue Scale (VAS) And WOMAC index

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Group 1 (40 people) will use alendronite. The duration of treatment will be 2 months, 70 mg will be administered orally weekly.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Control group: Group 2 (Placebo) (40 individuals). The form and type of the drug is the same. The treatment duration is 2 months, 70 mg will be administered orally weekly.

##### **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Rheumatology Clinic of Rafsanjan University of Medical Sciences

**Full name of responsible person**

Mahsa Hassanipour

**Street address**

Ali ibn Abi Talib Square, Ali ibn Abi Talib Hospital

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**Email**

mahsahasani@rums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Reza Vazirinejad

**Street address**

Central Organization of Rafsanjan University of Medical Sciences. Imam Ali Avenue,

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**Email**

rvazirinejad@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Rafsanjan 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**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Mahsa Hassanipour

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pharmacology

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

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### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

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**Email**

## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available