

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)

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+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

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Ali ibn Abi Talib Square, Ali ibn Abi Talib Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Reza Vazirinejad

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

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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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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