

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Evaluating the effects of oral Selenium as a adjuvant therapy on controlling clinical symptoms in rhumatoid arthritis Patients

Protocol summary

Study aim

Evaluation of the relationship between selenium consumption and the reduction of clinical symptoms and joint pain in patients with rheumatoid arthritis

Design

This study is a randomized, placebo-controlled, double-blind trial in 70 patients with arthritis rheumatoid that referred to rheumatology clinic of Iran University of Medical Sciences, Tehran.

Settings and conduct

The first group of patients with standard rheumatoid arthritis interventions and treatments, will receive century company selenium at a dose of 200 µg twice a day for 12 weeks and the second group will receive standard treatments with placebo. Placebo medicine is prepared by Barij Essence Pharmaceutical Company of Kashan. Placebo has all the components of the drug except selenium.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diagnosis of active arthritis rheumatoid; Patients more than 18 years and less than 65 years; Patients with moderate to severe active disease. Exclusion criteria: Patients with active infection; Patients with mild active disease.

Intervention groups

In intervention group, patients in addition to standard regimen for RA will receive selenium 200 µg twice a day for 12 weeks and placebo group will receive standard regimen with placebo.

Main outcome variables

Assessment of clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161204031229N4**

Registration date: **2021-07-17, 1400/04/26**

Registration timing: **prospective**

Last update: **2021-07-17, 1400/04/26**

Update count: **0**

Registration date

2021-07-17, 1400/04/26

Registrant information

Name

Azadeh Eshraghi

Name of organization / entity

Department of Clinical Pharmacy, Faculty of Pharmacy-International Campus, Iran University of Medica

Country

Iran (Islamic Republic of)

Phone

+98 86709

Email address

eshraghi.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-17, 1400/05/26

Expected recruitment end date

2021-11-11, 1400/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of oral Selenium as a adjuvant therapy on controlling clinical symptoms in rhumatoid arthritis Patients

Public title

Effect of Selenium on controlling clinical symptoms in rheumatoid arthritis Patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Active disease at the time of enrollment Stable renal function No liver dysfunction Ability to receive oral medication

Exclusion criteria:**Age**

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by permutation block method. In each block, according to the sample size, five patients are admitted. Random allocation help software is also used.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants in the study, including participants, clinical caregivers, researchers, etc., are kept blind. Of course, before starting the study, informed consent is obtained from the participants. But because drugs and placebo are similar in shape and different in content, practically no one knows their true nature.

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

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Trhran

Province

Tehran

Postal code

1449614535

Approval date

2021-02-13, 1399/11/25

Ethics committee reference number

IR.IUMS.REC.1399.1279

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

Rheumatoid arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

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

Assessment of clinical symptoms

Timepoint

Before studying, after 12 months

Method of measurement

Disease Activity Score, version 28 questionnaire

Secondary outcomes

empty

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

Intervention group: Standard regimen plus selenium 200 µg twice daily for 12 months.

Category

Prevention

2**Description**

Control group: Standard regimen without selenium

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasoole Akram Hospital

Full name of responsible person

Nahid Kianmehr

Street address

Niayesh St, Satar khan Av, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Email

kianmehr_2005@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Email

motevalian.a@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

Azade Eshraghi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2030

Email

eshraghi.a@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Azade Eshraghi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2030

Email

eshraghi.a@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Azade Eshraghi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2030

Email

eshraghi.a@iums.ac.ir

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