

# 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**

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+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

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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

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## Person responsible for scientific inquiries

### Contact

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Assistant professor

**Latest degree**

Ph.D.

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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