Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Public title
Effect of Ṡelenium 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Abbas Motevalian

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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
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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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