Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of selenium with placebo on disease activity and inflammatory factors and oxidative stress in patients with rheumatoid arthritis

Protocol summary

Study aim
The aim of this study is to determine the effect of selenium supplementation on disease activity and inflammatory factors and oxidative stress in rheumatoid arthritis patients

Design
A double-blind placebo-controlled clinical trial. Patients will be assigned to either a selenium supplement (n = 30) or a placebo (n = 30).

Settings and conduct
Among the patients with rheumatoid arthritis referred to the Beheshti Clinic, 60 patients will be selected based on inclusion and exclusion criteria. Participants and researchers are unaware of the allocation of study groups. Supplement and placebo tablets are similar in shape and size. Fasting blood samples will be taken from patients at baseline and 12 weeks after intervention

Participants/Inclusion and exclusion criteria
rheumatoid arthritis patients; ages 18 to 75 years who Exclusion criteria: Patients with infectious diseases, concomitant rheumatologic disease or hypertension

Intervention groups
Intervention group: 200 µg daily selenium for 12 weeks. Control group: placebo tablet daily for 12 weeks

Main outcome variables
Changes in disease activity, changes in clinical symptoms, lipid profiles, inflammatory factors, and changes in oxidative stress biomarkers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190924044869N1**
Registration date: **2020-06-14, 1399/03/25**
Registration timing: **registered_while_recruiting**
Last update: **2020-06-14, 1399/03/25**
Update count: **0**

Registration date
2020-06-14, 1399/03/25

Registrant information

Name
Fereshteh Taghvaee

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5531 6850

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sedaghat_h@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-20, 1398/12/01

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of selenium with placebo on disease activity and inflammatory factors and oxidative stress in patients with rheumatoid arthritis

Public title
Effect of Selenium supplementation in rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with active rheumatoid arthritis aged 18 to 75 years.

Exclusion criteria:

active infection high and moderate blood pressure (systolic pressure less than 140 and diastolic pressure less than 90 mmHg) smoking concurrent rheumatologic disease Hypothyroidism or hyperthyroidism Kidney or liver failure

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 66 by a random number generator (https://stattrek.com/statistics/random-number-generator.aspx) and patients were randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes. Supplements and placebos are in the same packaging at the Pharmaceutical company. Only the code is written on the packages. Patients and researchers do not know the type of intervention and after analyzing the data, packet codes are decoded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

committee of Kashan University of medical sciences

Street address

Ghotbe Ravandi Blvd

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2020-02-03, 1398/11/14

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.129

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

2

Description

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of

intervention
Method of measurement
Enzymatic kit

5

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive one Selenium tablet 200 microgram tablet daily for 12 weeks.
Category
Treatment - Drugs

2

Description
The control group will receive one placebo tablet daily for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Batol Zamani
Street address
Qotb-e-Ravandi Boulevard
City
Kashan
Province
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8115187159
Phone
+98 31 5554 0026
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zamani-b@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafshe
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research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Fereshte Taghvaee
Position
Associate
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact
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Other areas of specialty/work
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City
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Province
Isfehan
Postal code
8115187159
Phone
+98 31 5554 0021
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fsh.taghvaee@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
A portion of the data regarding demographics, anthropometric, and food variables, that are collected at the baseline of the study, and also the information on the main outcome will be shared.
When the data will become available and for how long
The start of the data access period will be one year after the publication of the result.
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
In order to conduct meta analysis studies
From where data/document is obtainable
Nasrin Sharifi, Nutrition Department, School of Medicine, Kashan University of Medical Sciences, Qotbe-e-Ravandi Blvd., Kashan, Iran Postal Code: 88715973474 E-mail: sharifi-na@kaums.ac.ir Tel: 00983155540021 Fax: 00983155620608
What processes are involved for a request to access data/document
An applicant can send a request for a data file by e-mail.

After reviewing the request, the data file will be sent to him/her after about three weeks would have passed from the date of the request

Comments