Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of selenium supplementation on disease activity, serum levels of some oxidative stress factors, anti-ds DNA antibody (Anti-ds DNA) and high sensitivity C-reactive protein (hs CRP) in patients with systemic lupus erythematosus (LES) .

Protocol summary

Study aim

Determining the effect of selenium supplementation on disease activity, oxidative stress, anti-ds DNA and hs CRP in patients with systemic lupus erythematosus

Design

A double-blind randomized clinical trial with a control group, with parallel groups, on 56 patients with systemic lupus erythematosus, with with randomization and double-blind method

Settings and conduct

Referred to Ahvaz rheumatology clinic in 2022, selection of 56 patients based on inclusion and exclusion criteria, randomization into two intervention and control groups, blinding of patients and researcher, coding by someone outside the study.

Participants/Inclusion and exclusion criteria

People are divided into two intervention and control groups. inclusion criteria include: age 15 to 60 years, having at least four clinical and immunological diagnostic criteria for systemic lupus erythematosus, body mass index equal to and less than 35 Non-entry criteria include: suffering from other autoimmune and rheumatological diseases, pregnancy and breastfeeding, severe liver diseases, severe renal failure, severe and active infections, taking selenium supplements in the last two months, recent excessive use of antioxidant supplements (such as vitamin C, vitamin E, omega 3, etc.) or their consumption during intervention, history of allergy to selenium supplements, suffering from other cancers

Intervention groups

supplement group : 28 people who received a tablet containing 200 micrograms of selenium daily for 8 weeks. placebo group: 28 people receiving a daily placebo pill containing corn starch for 8 weeks

Main outcome variables

Disease activity, hs-CRP, serum levels of Anti ds-DNA, oxidative stress factors (malondialdehyde, glutathione peroxidase, total antioxidant capacity)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210717051914N2**
Registration date: **2022-12-09, 1401/09/18**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-09, 1401/09/18**
Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

Hengameh Abrishamkar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of selenium supplementation on disease activity, serum levels of some oxidative stress factors, anti-ds DNA antibody (Anti-ds DNA) and high sensitivity C-reactive protein (hs CRP) in patients with systemic lupus erythematosus (LES) .

Public title
effect of selenium in systemic lupus erythematosus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 15 to 60 years Having at least four of the clinical and immunological diagnostic criteria for systemic lupus erythematosus Body mass index equal to and less than 35
Exclusion criteria:
Suffering from other autoimmune and rheumatological diseases Pregnancy and breastfeeding Severe liver diseases Severe renal failure Severe and active infections Taking selenium supplements during the last two months Recent excessive consumption of antioxidant supplements (such as vitamin C, vitamin E, omega 3, etc.) or their consumption during the intervention History of allergy to selenium supplements Other cancers Body mass index above 35
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization method will be used to assign people to study groups. Based on sextet blocks, people are assigned to two groups of receiving selenium supplement and placebo. In order to randomize the entry of samples into each of the groups, the package containing the supplement and placebo will be labeled as A and B. Before starting the study, the relevant packages are coded by a person other than the researcher as group A containing selenium supplement or placebo and group B containing selenium supplement or placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to reduce the possibility of information bias, a double-blind method will be used. In this way, both the patients and the researcher and the person evaluating the treatment results will be kept unaware of the type of treatment assigned to the people. Also, in order to reduce the possibility of selection bias, Allocation Concealment method or use of unit codes is used after randomization. In this way, all containers containing supplements and placebo, which are completely similar in appearance, are coded as A and B by someone outside the study, and breaking the code will be possible only by the person who did the numbering.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
1579461357
Approval date
2022-11-15, 1401/08/24
Ethics committee reference number
IR.AJUMS.REC.1401.357

Health conditions studied

1

Description of health condition studied
Systemic lupus erythematosus
ICD-10 code
M32.9
ICD-10 code description
Systemic lupus erythematosus, unspecified

Primary outcomes

1

Description
Disease activity

Timepoint
At the beginning and after 8 weeks of intervention
Method of measurement
By completing the questionnaire to measure the severity of systemic lupus erythematosus disease activity

2

Description
Anti-double-stranded DNA antibody
Timepoint
At the beginning and after 8 weeks of intervention
Method of measurement
Using the ELISA kit

3

Description
High-sensitivity C-reactive protein
Timepoint
At the beginning and after 8 weeks of intervention
Method of measurement
Using the ELISA kit

4

Description
Glutathione peroxidase
Timepoint
At the beginning and after 8 weeks of intervention
Method of measurement
Using the ELISA kit

5

Description
Malondialdehyde
Timepoint
At the beginning and after 8 weeks of intervention
Method of measurement
Using the ELISA kit

6

Description
Total antioxidant capacity
Timepoint
At the beginning and after 8 weeks of intervention
Method of measurement
Using the ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 28 people receiving tablets containing 200 micrograms of selenium (selenomethionine form), manufactured by Health Burst, one tablet daily for 8 weeks after meals
Category
Treatment - Drugs

2

Description
Control group: 28 people receiving placebo tablets containing corn starch, prepared by the growth center of Jundishapur University of Ahvaz, one tablet daily for 8 weeks after meals.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Doctor's office specializing in rheumatology
Full name of responsible person
Bizhan Helli
Street address
Golestan Blvd., Jundishapur University of Medical Sciences, Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mehrnoosh Zakerkish
Street address
Golestan Blvd., Jundi Shapur University of Medical Sciences, Ahvaz, Assistance of Research and Technology
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itc@ajums.ac.ir
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Hengameh Abrishamkar
Position
Masters student
Latest degree
Bachelor
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Nutrition
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Person responsible for updating data

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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