

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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)

##### Phone

+98 61 3321 9296

##### Email address

nutritionist.h.a@gmail.com

#### 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**

Khuzestan

**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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Ahvaz

#### **Province**

Khuzestan

#### **Postal code**

6135715794

#### **Phone**

+98 61 3311 0000

#### **Email**

helli-b@ajums.ac.ir

## **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

**Other areas of specialty/work**

Nutrition

**Street address**

Golestan Blvd., Jundishapur University of Medical Sciences, Faculty of Paramedicine

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Bizhan Helli

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

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**Email**

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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