

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### The effect of selenium supplementation on oxidative stress, clinical symptoms and mental health in patients with migraine

#### Protocol summary

##### Study aim

The aim of this study is to investigate the effect of selenium supplementation on clinical characteristics, oxidative stress, mental health and quality of life in migraine patients.

##### Design

Randomized, placebo-controlled, phase 3 on 72 patients. A four-block randomization method will be used.

##### Settings and conduct

This study will be conducted on migraine patients referring to the neurology clinic of Al-Zahra Hospital in Isfahan city. At the beginning and end of the 12th week, migraine symptoms, mental health status, and quality of life will be evaluated, and venous blood samples will be taken from the patients. Blinding will be done for patients and researchers.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria including: migraine diagnosis by a neurologist based on international classification of headache-3, age of 18 to 65 years, having at least two migraine attacks per month, and body mass index of 18.5-30. Exclusion criteria including: pregnancy and lactation, taking antioxidant supplements in the last 3 months, and having a medical history of infectious disorders, cardiovascular diseases, diabetes, liver and kidney diseases, other neurological diseases such as tension headache, epilepsy, Parkinson's and multiple sclerosis.

##### Intervention groups

The patients in the intervention group will receive a 200 microgram selenium tablet (Health Burst) daily for 12 weeks. Control group patients will receive a placebo tablet containing 200 microgram starch (Faculty of Pharmacy, Isfahan University of Medical Sciences) daily for 12 weeks.

##### Main outcome variables

Migraine symptoms, patients' quality of life, mental health, oxidative stress status

#### General information

##### Reason for update

Due to the strict selection of patients based on the inclusion and exclusion criteria, as well as the reluctance of some patients to participate in the study, the recruitment period has been extended than the period predicted in the previous protocol. Therefore, we considered it necessary to report the change made and correct the estimated date that the recruitment will be ended. Also, more explanations were added in some parts.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121216011763N60**  
Registration date: **2023-05-27, 1402/03/06**  
Registration timing: **registered\_while\_recruiting**

Last update: **2024-01-02, 1402/10/12**

Update count: **1**

##### Registration date

2023-05-27, 1402/03/06

##### Registrant information

###### Name

Gholamreza Askari

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2110

###### Email address

askari@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-22, 1402/03/01

**Expected recruitment end date**

2024-02-29, 1402/12/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of selenium supplementation on oxidative stress, clinical symptoms and mental health in patients with migraine

**Public title**

The effect of selenium on migraine

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Migraine diagnosis based on International Classification of Headache Disorders-3 Age of 18 to 65 years At least two migraine attacks per month BMI of 18.5 to 30 kg/m<sup>2</sup>

**Exclusion criteria:**

Pregnancy or lactation Taking antioxidant supplements 3 month before the intervention Suffering from infectious disorders, cardiovascular diseases, diabetes, liver and kidney diseases, other neurological disorders including tension headache, epilepsy, Parkinson and multiple sclerosis .

**Age**From **18 years** old to **65 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked***No information***Sample size**Target sample size: **72****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization of patients will be done using a four-block randomization method. For this purpose, people were classified into 4 states based on the variables of gender (female, male) and age (18-39, 40-65 years) and people with the same states were randomly assigned to intervention and placebo groups in a 1:1 ratio. Block randomization will be done using a list of random numbers generated by the website <https://www.sealedenvelope.com/simple> and by an independent researcher. Investigators and patients will remain blinded to allocation.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This is a double-blind randomized controlled trial. The selenium supplement and placebo are identical in terms of color, smell, shape, and size. They will be packaged in similar boxes and labeled A or B by an independent investigator. Both participants and the outcome assessor

will not be informed of the contents of the packages until the end of the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

The present study is the first to investigate the effect of selenium supplementation on oxidative stress, clinical symptoms, and mental health status in migraine patients.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Deputy of Research &amp; Technology of Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2023-03-11, 1401/12/20

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1401.404

**Health conditions studied****1****Description of health condition studied**

Migraine

**ICD-10 code**

G43

**ICD-10 code description**

Migraine

**Primary outcomes****1****Description**

Clinical characteristics of migraine (frequency, severity, and duration of migraine headaches)

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Visual analogue scale questionnaire

## 2

### **Description**

oxidative stress (malondialdehyde, nitric oxide, total oxidant status and total antioxidant capacity)

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

Kiazist biochemical kit

## **Secondary outcomes**

### 1

### **Description**

Mental health

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

DASS-21 questionnaire

### 2

### **Description**

Quality of life

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

MSQ and HIT-6 questionnaires

## **Intervention groups**

### 1

### **Description**

Intervention group: The patients will receive for 12 weeks a tablet containing 200 microgram selenomethionine (Health Burst) daily.

### **Category**

Treatment - Drugs

### 2

### **Description**

Control group: The patients will receive for 12 weeks a placebo tablet containing 200 microgram starch (The School of Pharmacy, Isfahan University of Medical Sciences, Isfahan) daily.

### **Category**

Placebo

## **Recruitment centers**

### 1

### **Recruitment center**

#### **Name of recruitment center**

Neurology clinic of Al-Zahra Hospital

#### **Full name of responsible person**

Dr. Gholamreza Askari

#### **Street address**

Soffeh Blvd

### **City**

Isfahan

### **Province**

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### **Postal code**

8174675731

### **Phone**

+98 31 3222 2127

### **Email**

askari@mui.ac.ir

## **Sponsors / Funding sources**

### 1

### **Sponsor**

#### **Name of organization / entity**

Esfahan University of Medical Sciences

#### **Full name of responsible person**

Dr. Gholamreza Askari

#### **Street address**

Deputy of search & Technology of Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

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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**

Esfahan 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**

Esfahan University of Medical Sciences

#### **Full name of responsible person**

Dr. Gholamreza Askari

#### **Position**

Professor

#### **Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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Dr. Gholamreza Askari

**Position**

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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