

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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/m2

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 & 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

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8174675731

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+98 31 3222 2127

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Askari

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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

Esfahan University of Medical Sciences

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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