

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Investigating the effect of co-supplementation with alpha-linolenic acid and L-carnitine on inflammatory status, oxidative stress, clinical symptoms, mental health and quality of life in women with migraine

#### Protocol summary

##### Study aim

Investigating the effect of co-supplementation with alpha-linolenic acid and L-carnitine on inflammatory status, oxidative stress, clinical symptoms, mental health and quality of life in women with migraine

##### Design

A controlled, randomized, triple-blind clinical trial with parallel groups, phase 3 on 80 women with migraine. Randomization based on the permuted blocks randomization according to age

##### Settings and conduct

The participants will be selected from women migraine patients who refer to the neurologist's office in Isfahan city. At the beginning and end of the study, venous blood samples, anthropometric measurements, questionnaires related to migraine, demographic information and socio-economic status of patients will be measured and recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in the study, diagnosed with migraine by a neurologist, age 20 to 50 years, at least one year has passed after migraine diagnosis. Exclusion criteria: Migraine with aura, suffering from chronic diseases, pregnancy and lactation, taking nutritional supplements in the past 3 months, taking anticoagulants, smoking, and following a special diet.

##### Intervention groups

Intervention: Daily supplement of alpha-linolenic acid (1000 mg of flaxseed oil, one capsule containing 350 mg of alpha-linolenic acid, Barij company) and supplement of L-carnitine (500 mg of L-carnitine, one tablet, Behta Daro company) Control group: Alpha-linolenic acid placebo (parafin oil, one capsule) and L-carnitine placebo (maltodextrin, one tablet) The duration of the intervention: 12 weeks

##### Main outcome variables

Clinical symptoms of migraine, oxidative stress and inflammatory status, mental health and quality of life

#### General information

##### Reason for update

Changing the block criteria in the randomization of participants

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121216011763N57**  
Registration date: **2023-03-29, 1402/01/09**  
Registration timing: **prospective**

Last update: **2024-09-08, 1403/06/18**

Update count: **2**

##### Registration date

2023-03-29, 1402/01/09

##### 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

2023-05-06, 1402/02/16

##### Expected recruitment end date

2023-11-21, 1402/08/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of co-supplementation with alpha-linolenic acid and L-carnitine on inflammatory status, oxidative stress, clinical symptoms, mental health and quality of life in women with migraine

**Public title**

The effect of co-supplementation with alpha-linolenic acid and L-carnitine in migraine

**Purpose**

Treatment

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

Patients who are willing to participate in the study  
Migraine diagnosis by a neurologist based on the International Classification of Headache Disorders-3 (ICHD-3) Age 20 to 50 years At least one year has passed since the migraine diagnosis

**Exclusion criteria:**

Migraine with aura Suffering from cardiovascular diseases, hypertension, diabetes, liver and kidney diseases, malignancies and other neurological disorders  
Pregnancy and lactation Taking nutritional supplements (including riboflavin, feverfew, magnesium and coenzyme Q10 in the last 3 months) Taking anticoagulants Following a special diet Smoking

**Age**

From **20 years** old to **50 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples will be randomly placed in one of the four intervention or control groups using permuted block randomization, with blocks of 4. In order to distribute patients into intervention and control groups, first, people are classified into two states in terms of age (less than 35 years/35 years and older). Then, people with the same conditions will be randomly assigned to one of the intervention and control groups. Also, the researcher evaluating the intended outcomes is unaware of the random allocation process and the type of treatment performed.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The study will be conducted as a three-blind study as follows: Medicines and placebo will be provided to all groups in completely identical containers without name labels, prepared in the same color and smell, and coded based on random allocation by the researcher. Therefore, none of the patients were aware of the assigned treatment and will not be informed until the end of the study. Also, the researcher evaluating the intended outcomes is unaware of the random allocation process and the type of treatment performed.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2023-03-12, 1401/12/21

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1401.406

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

Migraine

**ICD-10 code**

Migraine w

**ICD-10 code description**

G43.0

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

clinical symptoms of migraine (severity, frequency, duration of migraine attacks)

## **Timepoint**

At baseline and after 12 weeks

## **Method of measurement**

Visual Analogue Scale (VAS) questionnaire and clinical examination

## **2**

### **Description**

Serum levels of C-reactive protein (CRP)

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

Enzyme-linked immunosorbent assay (ELISA) kits

## **3**

### **Description**

serum level of superoxide dismutase (SOD)

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

biochemical kit of KiaZist Co.

## **4**

### **Description**

Serum level of malondialdehyde (MDA)

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

biochemical kit of KiaZist Co.

## **5**

### **Description**

total antioxidant capacity

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

biochemical kit of KiaZist Co.

## **6**

### **Description**

Serum level of Nitric Oxide

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

biochemical kit of KiaZist Co.

## **7**

### **Description**

Mental health (Stress, anxiety, depression)

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

Depression, Anxiety and Stress Scale-21 questionnaire (DASS-21)

## **8**

### **Description**

Quality of Life of Migraine Patients

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

Migraine -Specific Quality of Life (MSQ) questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: An alpha-linolenic acid supplement (daily 1000 mg flaxseed oil, one capsule containing 350 mg alpha-linolenic acid) and L-carnitine supplement (500 mg L-carnitine)

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Alpha-linolenic acid placebo (paraffin oil, one 1000 mg capsule per day) and L-carnitine placebo (maltodextrin, one 500 mg tablet per day)

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Neurologist's office located in Isfahan Khurshid Clinic

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

Dr. Gholamreza Askari

##### **Street address**

khurshid medical educational research complex,  
Ostandari Street, Isfahan

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8145833117

##### **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 Research & Technology of Isfahan  
University of Medical Sciences, Hezar Jarib Street,  
Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 3060

**Email**

askari@mui.ac.ir

**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

**Street address**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

009837923060

**Email**

askari@mui.ac.ir

**Person responsible for scientific 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

**Street address**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 3060

**Email**

askari@mui.ac.ir

**Person responsible for updating data****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

**Street address**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 3060

**Email**

askari@mui.ac.ir

## **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