

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

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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

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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

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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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Deputy of Research & Technology of 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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Askari

Position

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

Esfahan University of Medical Sciences

Full name of responsible person

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