

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Investigating the effect of supplementation with Moringa Oleifera on inflammatory status, oxidative stress, clinical symptoms, mental health and quality of life in patients with migraine

Protocol summary

Study aim

Investigating the effect of supplementation with Moringa Oleifera on inflammatory status, oxidative stress, clinical symptoms, mental health and quality of life in patients with migraine

Design

A randomized, double-blind, placebo-controlled phase III clinical trial with parallel groups will be conducted on 80 patients with migraine aged 20–50 years. After obtaining written informed consent, participants will be allocated to the Moringa oleifera supplement group or the placebo group in a 1:1 ratio. Randomization will be performed using a block randomization method via the Sealed Envelope website.

Settings and conduct

This is a randomized, double-blind, parallel clinical trial involving migraine patients from Isfahan neurology clinics. Participants will return unused supplement packages at each visit. Baseline and end-of-study data collection includes venous blood samples, anthropometric measurements, migraine questionnaires, demographic, and socioeconomic information.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate, neurologist-confirmed migraine (ICHD-3), and age 20–50 years. Exclusion criteria: Supplement non-adherence (<80%), hypersensitivity, missed follow-ups, pregnancy or lactation, use of specific supplements (riboflavin, magnesium, CoQ10, Feverfew) in the past 3 months, smoking, or adherence to a special/restrictive diet.

Intervention groups

Intervention group: Participants will receive 1,000 mg of Moringa oleifera daily (two 500-mg tablets) produced by Sinafaravar Pharmaceutical Co. for 12 weeks. Control group: Participants will receive a daily placebo (two 500-mg starch-based tablets) identical in shape, color, and packaging to the Moringa oleifera supplement, also

for 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

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N66**

Registration date: **2026-05-05, 1405/02/15**

Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**

Update count: **0**

Registration date

2026-05-05, 1405/02/15

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

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of supplementation with Moringa Oleifera on inflammatory status, oxidative stress, clinical symptoms, mental health and quality of life in patients with migraine

Public title

The effect of Moringa Oleifera supplement in migraine

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient must agree to participate in the study. The diagnosis of migraine must be confirmed by a neurologist according to the ICHD-3 criteria. The patient must be aged between 20 and 50 years.

Exclusion criteria:

Non-compliance with dietary recommendations and supplements, defined as consuming less than 80% of the prescribed supplement. Development of a reaction or sensitivity to the prescribed supplement. Failure to attend follow-up visits at different stages of the study. Diagnosis of tension-type headaches. Diagnosis of gastrointestinal disorders such as Crohn's disease or ulcerative colitis, or other neurological disorders. Pregnancy or lactation. Use of nutritional supplements, including probiotics or prebiotics, within the last three months. Following a special diet. Use of antibiotics or antacid drugs within the past three months.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will conduct based on <https://www.sealedenvelope.com/simple-randomiser/v1/lits>. Each block have capacity for 4 subjects. Then, within each block, subjects will be randomly assigned to treatment or placebo. Random assignment will be done using a random chain will be extracted from the site.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind clinical trial (participant, researcher). Inulin supplement and placebo (identical from color, shape and odor) will be packaged in similar boxes and the researcher and patients will not be informed of the contents of the packs until the end of the study.

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

2026-04-20, 1405/01/31

Ethics committee reference number

IR.MUI.PHANUT.REC.1405.018

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

Migraine

ICD-10 code

Migraine

ICD-10 code description

G43

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

Secondary outcomes

1

Description

Depression, stress, anxiety

Timepoint

At baseline and after 12 weeks

Method of measurement

DASS-21 questionnaire

2

Description

Quality of Life in Migraine Patients

Timepoint

At baseline and after 12 weeks

Method of measurement

Migraine -Specific Quality of Life (MSQ) questionnaire

3

Description

Physical activity

Timepoint

At baseline and after 12 weeks

Method of measurement

International Physical Activity Questionnaire (IPAQ)

4

Description

Anthropometric indices

Timepoint

At baseline and after 12 weeks

Method of measurement

Seca scale and portable stadiometer

5

Description

Serum Nitric Oxide

Timepoint

At baseline and after 12 weeks

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) kits

6

Description

Total antioxidant capacity

Timepoint

At baseline and after 12 weeks

Method of measurement

Biochemical kit of KiaZist Co.

7

Description

Total oxidant status

Timepoint

At baseline and after 12 weeks

Method of measurement

Biochemical kit of KiaZist Co.

8

Description

serum levels of High sensitive C-reactive protein (Hs-CRP)

Timepoint

At baseline and after 12 weeks

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) kits

9

Description

Serum lactate levels

Timepoint

At baseline and after 12 weeks

Method of measurement

Biochemical kit of KiaZist Co.

10

Description

Serum malondialdehyde levels

Timepoint

At baseline and after 12 weeks

Method of measurement

Biochemical kit of KiaZist Co.

11

Description

Serum interleukin-6 levels

Timepoint

At baseline and after 12 weeks

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) kits

Intervention groups

1

Description

Intervention group: Participants will receive 1000 mg of Moringa oleifera supplement daily (two 500 mg tablets) for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Participants will receive two 500-mg placebo tablets containing starch daily for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology clinic

Full name of responsible person

Dr. Gholamreza Askari

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Khorshid medical educational research complex,
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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**

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Dr. Gholamreza Askari

Position

Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Dr.Gholamreza Askari

Position

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Other areas of specialty/work

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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