Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Not yet 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/lists. 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
Isfahan
Province
Isfehan
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, 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 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 updating data

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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