Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of inulin supplementation on inflammatory status, oxidative stress, intestinal permeability, clinical features and mood in women with migraine

Protocol summary

Study aim
The effect of inulin supplements on inflammatory status, oxidative stress, intestinal permeability, clinical symptoms and mood in women with migraine

Design
A randomized controlled clinical trial with parallel groups, double-blind, randomized

Settings and conduct
The present study is a double-blind, randomized, parallel clinical trial. The participants will be selected from women migraine patients who refer to the neurology clinic 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: Patients who agree to participate in the study Diagnosis of migraine by a neurologist according to ICHD-3. Aged between 20 to 50 years old Exclusion criteria: Non-compliance with dietary recommendations and supplements (Use less than 80% of the prescribed supplement) Reaction and sensitivity to the prescribed supplement Lack of referral in different stages of study, pregnancy and lactation, taking nutritional supplements in the past 3 months, taking anticoagulants, smoking, and following a special diet.

Intervention groups
Intervention group (N=40): Inulin, with commercial name Frutafit® TEX, Sensus/Netherlands. The supplement will be given to patients in 10 grams packs for 12 weeks. Control group: Maltodextrin powder, 10 grams per day.

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

General information

Reason for update
Exclusion criteria are very restricting, which may affect the credibility and universality of the study results

Acronym

IRCT registration information
IRCT registration number: **IRCT20121216011763N58**
Registration date: **2023-04-23, 1402/02/03**
Registration timing: **prospective**

Last update: **2023-09-17, 1402/06/26**
Update count: **2**

Registration date
2023-04-23, 1402/02/03

Registrant information

Name
Gholamreza Askari

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 1792 2110

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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

The effect of inulin supplementation on inflammatory status, oxidative stress, intestinal permeability, clinical features and mood in women with migraine

Public title

The effect of inulin supplement in migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who agree to participate in the study Diagnosis of migraine by a neurologist according to ICHD-3 Aged between 20 to 50 years old

Exclusion criteria:

Non-compliance with dietary recommendations and supplements(Use less than 80% of the prescribed supplement) Reaction and sensitivity to the prescribed supplement Lack of referral in different stages of study Suffering from tension headaches Suffering from gastrointestinal disorder like crohn’s and ulcerative colitis and other neurological disorders Pregnancy and lactation Taking nutritional supplements (including probiotics, prebiotics in the last 3 months) Following a special diet Antibiotics and anti-acids drugs in three months past

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

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

2023-03-15, 1401/12/24

Ethics committee reference number

IR.MUI.RESEARCH.REC.1401.416

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

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-21questionnaire

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 levels of Zonulin
Timepoint
At baseline and after 12 weeks
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kits

6

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

7

Description
Serum Nitric Oxide
Timepoint
At baseline and after 12 weeks
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kits

8

Description
Total antioxidant capacity
Timepoint
At baseline and after 12 weeks
Method of measurement
biochemical kit of KiaZist Co.

9

Description
Total oxidant status
Timepoint
At baseline and after 12 weeks
Method of measurement
biochemical kit of KiaZist Co.

Intervention groups

1

Description
Intervention group: one pack of 10 grams of inulin daily for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: one pack of 10 grams of maltodextrin daily for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology clinic
Full name of responsible person
Dr. Gholamreza Askari
Street address
khorshid medical educational research complex, Ostandari Street, Isfahan
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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

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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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Position

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Latest degree

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Person responsible for updating data

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Position

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Latest degree

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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