

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### 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**  
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/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

Isfahan

#### Province

Isfahan

#### 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**

khoshid 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**

+98 913 266 3418

**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**

+98 913 266 3418

**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**

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 1792 2110

**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