

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim

The effect of synbiotic 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 target population includes those with migraines referred to the khorshid Clinic and Imam Musa Sadr Clinic who are diagnosed according to the criteria of the International Headache Society (HIS) by a neurologist. Split and study for 12 weeks. Before and after the intervention, severity of headache, frequency of headache and duration of headache, serum Zonulin level, serum nitric oxide level, serum Hs-CRP level, Total antioxidant capacity, Total oxidant status, depression, stress, anxiety and quality of life of migraine patients will be measured. To double-blind this study, all capsules were coded as A and B prior to study initiation.

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

Intervention groups

روزانه دو عدد کپسول سین بیوتیک 500 (N=40) افراد گروه مداخله میلی گرم نیم ساعت قبل از وعده شام و نهار برای 12 هفته

Main outcome variables

Migraine severity score; migraine frequency; duration of migraine; Hs-CRP level, Zonulin level, nitric oxide level, total antioxidant capacity, total oxidant status, depression, stress, anxiety, quality of life

General information

Reason for update

grammar errors in title

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N45**

Registration date: **2020-04-22, 1399/02/03**

Registration timing: **prospective**

Last update: **2020-11-16, 1399/08/26**

Update count: **1**

Registration date

2020-04-22, 1399/02/03

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

2020-07-22, 1399/05/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

The effect of synbiotic 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

Age

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

Gender

Female

Phase

N/A

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/li> sts. 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). synbiotic 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

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8135798111

Approval date

2020-03-04, 1398/12/14

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.752

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

Migraine symptoms (severity, frequency, duration of migraine)

Timepoint

At baseline and after 12 weeks

Method of measurement

Questionnaire (Visual analogue scale (VAS) and Clinical examination)

2

Description

Serum levels of Zonulin

Timepoint

At baseline and after 12 weeks

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) kits

3

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

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

Serum Nitric Oxide

Timepoint

At baseline and after 12 weeks

Method of measurement

biochemical kit of KiaZist Co.

4

Description

Total antioxidant capacity

Timepoint

At baseline and after 12 weeks

Method of measurement

biochemical kit of KiaZist Co.

5

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: Two capsule of synbiotic 500 mg daily half an hour before dinner and lunch for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Two capsule of starch 500 mg daily half

an hour before dinner and lunch for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid clinic

Full name of responsible person

Gholamreza Askari

Street address

Ostandari St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 1792 2110

Email

askari@mui.ac.ir

2

Recruitment center

Name of recruitment center

Imam Musa Sadr Clinic

Full name of responsible person

Gholamreza Askari

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Foroughi St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezar Jarib

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Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.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

Abed ghavami

Position

Student

Latest degree

Master

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

Gholamreza Askari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Name of organization / entity

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Other areas of specialty/work

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Major part of information will be available for population.

When the data will become available and for how long

12 months after publication
To whom data/document is available
Available for people working in academic institutions
Under which criteria data/document could be used
To conduct similar studies
From where data/document is obtainable

askari@mui.ac.ir
What processes are involved for a request to access data/document
The data will be sent as soon as possible, after receiving the request
Comments