Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Synbiotic Supplementation on the Migraine Headache Characteristics in Adults

Protocol summary

Summary

Given the high prevalence of migraine worldwide and the lack of absolute treatment for it, we designed the current double blind, placebo-controlled trial to investigate the effects of 8-week supplementation with Protexin Synbiotic / placebo on duration, severity and frequency of migraine attacks as well as the number of analgesics used by patients. The inclusion criteria for participating in the study are as follows: consuming any type of fortified foods with probiotics in the last two months while exclusion criteria are taking any antipsychotic and antibiotic medications in the last two months . The study population consists of 100 patients of which 25 chronic and 25 episodic migraineurs will receive two capsules of protexin synbiotic supplements each day and 25 chronic and 25 episodic migraineurs will receive 2 capsules of placebo daily for 8 weeks. We will ask from all participants to keep up their routine medical treatment and normal diet without any change during the study. The efficacy of the intervention will be assessed using MIDAS and VAS in addition to measuring changes in frequency and severity of migraine obtained from headache diaries of patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706239157N6**
Registration date: **2017-07-26, 1396/05/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-26, 1396/05/04

Registrant information

Name

Prof Mansoureh Togha

Name of organization / entity

Neurology department, Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

School of Nutrition Sciences and Food Technology, National Nutrition and Food Technology Research Institute, Shaheed Beheshti University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-07-06, 1396/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Synbiotic Supplementation on the Migraine Headache Characteristics in Adults

Public title

Effects of Synbiotic Supplementation on Migraine Headache

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in the study;

Age range between 18 to 60 years old; Diagnosis of chronic and episodic migraine headache according to the International Classification of Headache Disorders, 3rd edition (ICHD3 beta) criteria; Passing more than three months from migraine diagnosis; Migraine headache with more than 15 attacks per month for chronic migraine patients; Migraine headache with 3-15 attacks per month for episodic migraine patients; Not taking a synbiotic supplement or foods which fortified by Synbiotic two months before entering the study. Exclusion criteria: Taking anti-psychotic drugs and/or antibiotic drugs during 2 months before the study; Pregnancy (or having a planned pregnancy); Lactation; Unwillingness to participate or continue the study.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
School of Nutrition Sciences and Food Technology, National Nutrition and Food Technology Research In

Street address
West Arghavan, Farahzadi BLV, Shahrak Gharb

City
Tehran

Postal code

Approval date
2016-08-27, 1395/06/06

Ethics committee reference number
IR.SBMU.nnftri.Rec.1395.66

Health conditions studied

1

Description of health condition studied
Chronic and Episodic Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
severity of migraine headache

Timepoint
before and two months after the intervention

Method of measurement
headache diary and examination by neurologist

2

Description
frequency of migraine attacks per month

Timepoint
before and two months after the intervention

Method of measurement
headache diary and examination by neurologist

3

Description
duration of migraine headache

Timepoint
before and two months after the intervention

Method of measurement
headache diary and examination by neurologist

Secondary outcomes

1

Description
the number of abortive drugs taken

Timepoint
before and two months after the intervention

Method of measurement
questionnaire

Intervention groups

1

Description
Synbiotic Group: Of 100 migraine patients, 25 subjects with chronic migraine and 25 subjects with episodic migraine will receive 2 capsules of protexin synbiotic supplement daily for 8 weeks. The supplement constituents are as fallows : Lactobacillus Casei, Lactobacillus Rhamnosus, Streptococcus thermophiles, Bifidobacterium brevis, Lactobacillus acidophilus, Bifidobacterium lehman, Lactobacillus bulgaricus,

Fructooligosaccharides (FOS) and Synbiotic culture media.

Category

Treatment - Drugs

2

Description

Control Group: Of 100 migraine patients, 25 subjects with chronic migraine and 25 subjects with episodic migraine will receive 2 capsules of placebo with the same smell and taste as protexin supplement for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital, Headache Clinic and Headache Research Center

Full name of responsible person

Maryam Seifi

Street address

Sina Hospital, Hasan Abad Sq., Imam Khomeini Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Morteza Abdollahi

Street address

West Arghavan, Farahzadi BLV, Shahrak Gharb

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nutrition Sciences and Food Technology, National Nutrition and Food Technology Research In

Full name of responsible person

Dr Soodeh Razeghi Jahromi

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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PhD in Nutritional sciences

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Full name of responsible person

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty