Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of low FODMAP (Fermentable, Oligo-, Di-, Mono-saccharides and Polyols) diet with glutamine supplement versus placebo on clinical outcomes, quality of life and intestinal permeability in patients with irritable bowel syndrome

Protocol summary

Study aim

Effect of the low-FODMAP(Fermentable, Oligo-, Di-, Mono-saccharides, and Polyols) diet with L-glutamine supplementation compared with placebo on clinical symptoms, quality of life and intestinal permeability in patients with irritable bowel syndrome

Design

Randomized Clinical Trial double-blind

Settings and conduct

patients with irritable bowel syndrome referring to Imam Khomeini Hospital, if they wish to participate in the study informed consent of them will be taken. Patients were randomized to receive a l-glutamine plus a low FODMAP diet or low FODMAP diet (and placebo) for 6 weeks. Before and after the intervention blood sample will be collected and scores will be evaluated for IBS symptoms. the study is double blind

Participants/Inclusion and exclusion criteria

ages 18-70; Patients with irritable bowel syndrome; Body Mass Index in range (18-25); Lack of any organic intestinal disease and intestinal infection; No medical history of chronic gastrointestinal and colorectal disease; Lack of any major bowel surgery; Lack of medical history of liver and kidney disorders; No regular use of laxative and anti-diarrhea medications.

Intervention groups

patients will receive a supplement or placebo with a low fodmap diet for 6 weeks depending on the group they are in. Patients in the supplement group will receive L-glutamine powder, and the placebo group will receive the iso whey protein powder which is similar in shape and color to the supplement. (both of them 5 g three times daily in 230 ml of water)

Main outcome variables

Abdominal pain intensity, Abdominal pain frequency, Abdominal distension, Satisfaction with bowel habits, Interference with community function, Defecation frequency, Defecation consistency, quality of life

General information

Reason for update

This update was performed to correct an error in the primary outcome section as well as changes in study design due to the coronavirus pandemic. The effective time period for receiving the diet and supplement according to previous studies is 6 to 8 weeks. This time was reduced from 8 weeks to 6 weeks to reduce face-to-face visits. The age range was changed to 18-70. Because the number of patients with irritable bowel syndrome over the age of 60 who refer to gastrointestinal clinics is high.

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N28**
Registration date: **2020-04-11, 1399/01/23**
Registration timing: **prospective**

Last update: **2021-01-09, 1399/10/20**
Update count: **1**

Registration date

2020-04-11, 1399/01/23

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences, National Institute of Nutrition Research

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 0824

Email address
hekmat@sina.tums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-06-20, 1399/03/31
Expected recruitment end date
2021-02-18, 1399/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of low FODMAP (Fermentable, Oligo-, Di-, Mono-saccharides and Polyols) diet with glutamine supplement versus placebo on clinical outcomes, quality of life and intestinal permeability in patients with irritable bowel syndrome

Public title
The effect of glutamine on clinical outcomes, quality of life and intestinal permeability in patients with irritable bowel syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with irritable bowel syndrome, according to a gastroenterologist diagnosed according to ROME IV criteria (having at least one day a week over the past 3 months for at least two of the following: 1- related to Defecation; 2- related to the frequency of defecation, 3- related to changes in stool shape and consistency, and no pathological findings in gastrointestinal Body Mass Index in range (18-25) Lack of any organic intestinal disease (diagnosed by last 5 years ago colonoscopy) and intestinal infection (diagnosed by stool culture) Lack of medical history of chronic gastrointestinal and colorectal disease Lack of any major bowel surgery Lack of medical history of liver disorders Absence of regular use of laxatives or antidiarrheal drugs No chronic use of corticosteroids and immunosuppressants No usage of drugs that modifying the digestive motility such as metoclopramide, cisapride, diphenoxylate No usage of drugs that increased bleeding of intestinal mucosa such as aspirin, warfarin and heparin Absence of nicotine and its derivatives use in the last 6 months No usage of NSAIDs and aspirin in last week (influence on gut permeability) Absence of severe mental or behavioral disorder Lack of medical history of kidney disorders
Exclusion criteria:
Not agree to entering the study Consumption of artificial sweeteners (effect on intestinal permeability) 2 days before entering the study
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The method used in this study to create a randomization process is simple randomization, so we utilize random number table. Beginning of the study, each person is randomly assigned to one of the 2 study groups according to the randomized distribution table.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients will receive a supplement or placebo with a low fodmap diet for 6 weeks depending on the group they are in. Patients in the supplement group will receive L-glutamine powder, and the placebo group will receive the iso whey protein powder which is similar in shape and color to the supplement. 5 g three times daily in 230 ml of water. Before starting the study, powdered cans are coded by a person other than the researcher into group A and group B to the purpose of not informing the researcher of the type of powder used by each group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1981619573

Approval date
2020-01-04, 1398/10/14
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1398.083

Health conditions studied

1

Description of health condition studied
irritable bowel syndrome
ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Irritable Bowel Syndrome symptom severity score
Timepoint
Beginning and end of study
Method of measurement
Irritable Bowel Syndrome symptom severity scale Questionnaire

Secondary outcomes

1

Description
Quality of life
Timepoint
Beginning and end of study
Method of measurement
Irritable bowel syndrome quality of life Questionnaire

2

Description
serum zonulin
Timepoint
Beginning and end of the study
Method of measurement
Elisa kit

3

Description
Abdominal pain intensity
Timepoint
Beginning and end of the study
Method of measurement
Visual Analogue Scale

4

Description
Abdominal pain frequency
Timepoint
Beginning and end of the study
Method of measurement
Questionnaire

5

Description
Abdominal distension
Timepoint
Beginning and end of the study
Method of measurement
Visual Analogue Scale

6

Description
Satisfaction with bowel habits
Timepoint
Beginning and end of the study
Method of measurement
Visual Analogue Scale

7

Description
Interference with community function
Timepoint
Beginning and end of the study
Method of measurement
Visual Analogue Scale

8

Description
Defecation frequency
Timepoint
Beginning and end of study
Method of measurement
Questionnaire

9

Description
Defecation consistency
Timepoint
Beginning and end of study
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: will receive15 g (5 grams three times a day) L- glutamine supplement plus low FODMAP diet for 6 weeks
Category
Treatment - Other

2

Description

Control group: will receive 15 g (5 grams three times a day) iso whey supplement plus low FODMAP diet for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Naser Ebrahimi Daryani

Street address

Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

nutrition@sbmu.ac.ir

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Hekmatdoost

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

West Arghavan, Shahrak Gharb

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2293 0824

Fax

Email

a_hekmat2000@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Hekmatdoost

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2293 0824

Fax

+98 21 2236 0656

Email

a_hekmat2000@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

samira rastgoo goosheh

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

samiraa.rastgoo@gmail.com

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