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 and without gluten on clinical outcomes and quality of life in patients with irritable bowel syndrome

Protocol summary

Study aim

The effect of low FODMAP (Fermentable, Oligo-, Di-, Mono-saccharides And Polyols) diet with and without gluten on clinical outcomes and quality of life in patients with irritable bowel syndrome

Design

A randomized, blinded, controlled clinical trial with a parallel group، design of 501 patients, , and the table of random numbers was used for the randomization.

Settings and conduct

patients with irritable bowel syndrome referring to Erfan 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 18-65; 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

In this study، patients will receive 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 5gr of gluten and the placebo group will recevie the 5 gr of rice flour which is similar in shape and color to the supplement , once a day and in the form of dissolved 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

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N29**
Registration date: **2020-06-01, 1399/03/12**
Registration timing: **prospective**

Last update: **2020-06-01, 1399/03/12**
Update count: **0**

Registration date

2020-06-01, 1399/03/12

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

2020-07-10, 1399/04/20

Expected recruitment end date

2021-03-20, 1399/12/30

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 and without gluten on clinical outcomes and quality of life in patients with irritable bowel syndrome

Public title

the effect of gluten on clinical outcomes and quality of life in patients with irritable bowel syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years 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 gasrtointestinal and colorectal disease Lack of any major bowel surgery Absence of regular use of laxatives or anti diarreheal drugs No chronic use of corticosteroids and immunosuppressants No usage of drugs that modifying the digestive motility such as metoclopramide, cisapride, diphenoxylates No usage of drugs that increased bleeding of intestinal mucosa such as aspirin, warfarin and heparin Lack of pregnancy or breastfeeding،athlete or hospitalization Absence of severe mental or behavioral disorder Absence of nicotine and its derivatives use in the last 6 months No usage of NSAIDs and aspirin in last week (effect on gut permeability)

Exclusion criteria:

consumption of artificial sweeteners(effet on intestinal permeability) 2 days before entering the study not agree to entering the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study، in order to the randomization process، a simple randomization is used by using a table of random numbers.before begining the study،each person is placed in one of the intervention or placebo groups based on a simple random division table.we have considered a two-digit code for the number of sample size numbers, and selected the start point by referring to the table, and based on the adjacent two-digit number, moved in the direction of the row, and we choose the first two-digit number less than 50 as the first smple and we'll continue to do this until the samples reach 50.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study، patients will receive 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 5gr of gluten and the placebo group will recevie the 5 gr of rice flour which is similar in shape and color to the supplement , once a day and in the form of dissolved in 230 ml of water. 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

Ethicts committe of Shahid Beheshti University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2020-01-05, 1398/10/15

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1399.010

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

Quality of life

Timepoint

Beginning and end of study

Method of measurement

Irritable Bowel Syndrome Quality of Life Quality of Life Questionnaire

Secondary outcomes

1

Description

Irritable Bowel Syndrome- Symptom Severity Score

Timepoint

Beginning and end of study

Method of measurement

Questionnaire (IBS_SSS)

2

Description

Abdominal pain intensity

Timepoint

Beginning and end of study

Method of measurement

Visual Analogue Scale

3

Description

Abdominal pain frequency

Timepoint

Beginning and end of study

Method of measurement

Questionnaire

4

Description

Abdominal distention

Timepoint

Beginning and end of study

Method of measurement

Visual Analogue Scale

5

Description

Satisfaction with bowel habits

Timepoint

Beginning and end of study

Method of measurement

Visual Analogue Scale

6

Description

Interference with community function

Timepoint

Beginning and end of study

Method of measurement

Visual Analogue Scale

7

Description

Defecation frequency

Timepoint

Beginning and end of study

Method of measurement

Questinnaire

8

Description

Defecation consistency

Timepoint

Beginning and end of study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive 5 gr gluten powder (includes packages of containing 5 gr of measure) once a day , and dissolved in 230 ml water plus a low FODMAP diet for 6 weeks. At first, the subject, objectives and method of the study are explained to patients with irritable bowel syndrome who meet the inclusion criteria, then, if they wish a written consent will be obtained from them.the diet will be explained to the patients, also at the beginning of the study, the height and weight of each patient are measured and BMI will be obtained using the formula (weight in kg divided by height in meters squared).a valid questionnaire for clincal symptomes and quality of life is completed at the beginning and end of the study. in this study, to checking of the patients' diet, at the end of the second and sixth weeks, 24-hours dietary recall is taken from patients for three days. 24-hours dietary recall questionnaires will be analyzed using N4 nutritinal software.in this stydy, patients will be monitored by call almost once a week due to the follow-up of patients the from diet and if the diet is not followed, they will be excluded from the study.

Category

Other

2

Description

Control group: Patients in the control group will receive 5 gr rice flur (includes packages of containing 5 gr of measure) once a day , and dissolved in 230 ml water

plus a low FODMAP diet for 6 weeks. At first, the subject, objectives and method of the study are explained to patients with irritable bowel syndrome who meet the inclusion criteria, then, if they wish a written consent will be obtained from them.the diet will be explained to the patients, also at the beginning of the study, the height and weight of each patient are measured and BMI will be obtained using the formula (weight in kg divided by height in meters squared).a valid questionnaire for clincal symptomes and quality of life is completed at the beginning and end of the study. in this study, to checking of the patients' diet, at the end of the second and sixth weeks, 24-hours dietary recall is taken from patients for three days. 24-hours dietary recall questionnaires will be analyzed using N4 nutritinal software.in this stydy, patients will be monitored by call almost once a week due to the follow-up of patients the from diet and if the diet is not followed, they will be excluded from the study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Erfan Hospital

Full name of responsible person

Shahram Agah

Street address

Erfan Hospital, Shahid Riazi Bakhshayesh St., sa'adat Abad

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2302 1000

Email

info@erfanhospital.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

Email

a_hekmat2000@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Hekmatdoost

Position

دانشیار

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address
No.7, Wast Arghavan .,Farahzadi Blvd.,Qods Town, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1981619573

Phone
+98 21 2293 0824

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
Fatemeh Mohseni

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
No. 7, Mikhak Dead End ,The First of Eqbal Pur St.,Simon Bolivar Blvd., The End of Ashrafi Esfehani Hwy, Punak

City
Tehran

Province
Tehran

Postal code
1477773683

Phone
+98 21 4480 0079

Email
fh.mohseni73@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