

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 receive 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

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Name of organization / entity

Shahid Beheshti University of Medical Sciences,
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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 gastrintestinal and colorectal disease Lack of any major bowel surgery Absence of regular use of laxatives or anti diarrheal drugs No chronic use of corticosteroids and immunosuppressants No usage of drugs that modifying the digestive motility such as metoclopramide, cisapride, diphenoxyates 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(efet 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 receive 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

Questionnaire

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 clinical symptoms 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 study, 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 flour (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 clinical symptoms 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 study, 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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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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