

# 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

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 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(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 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

**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@sbm.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