

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The efficacy of gluten free diet on clinical symptoms and signs, quality of life, and inflammatory factors in patients with irritable bowel syndrome under low FODMAP (Fermentable, Oligo-, Di-, Mono-saccharides And Polyols) diet

Protocol summary

Study aim

To investigate and compare the efficacy of administration of gluten free diet on clinical symptoms and signs, quality of life, and inflammatory factors in patients with irritable bowel syndrome under low FODMAP diet

Design

Randomized Clinical Trial

Settings and conduct

In this study, patients with irritable bowel syndrome referring to Taleghani Hospital, if they wish to participate in the study informed consent of them will be taken. All patients undergo low FODMAP+strict gluten free diet after delivery of blood and stool samples for 6 weeks. In the second 6 weeks, they will be randomly assigned to one of the three intervention and control groups, and the blood and stool samples and scores will be evaluated for the evaluation of IBS symptoms.

Participants/Inclusion and exclusion criteria

1)18-65 years 2) Patients with irritable bowel syndrome, according to gastroenterologist diagnosed according to the ROME- IV criteria 3) lack of any organic intestinal disease(diagnosed by last 5 years ago colonoscopy) and intestinal infections(diagnosed by stool culture). 4) No medical history of chronic gastrointestinal and colorectal disease Absence of any major bowel surgery 5) Absence of regular use of laxatives or antidiarrheal drugs

Intervention groups

1) Group I: will receive food products with 8g/day gluten for first 2 weeks, 16g/day gluten for second 2 weeks, following 32g/day gluten for third 2 weeks. 2) Group II: will continue low FODMAP+ strict (Gluten free) diet for 6 weeks. 3) Control group: will receive free diet for 6 weeks.

Main outcome variables

Age, Sex, Smoking, Weight, Height, Body Mass

Index(BMI), Total energy intake, Total carbohydrate intake, Total fat intake, Total protein intake, Total fiber intake, Total SFA intake, Total MUFA intake, Total PUFA intake, serum level of IL-6 and INF- γ

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N26**

Registration date: **2018-10-20, 1397/07/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-20, 1397/07/28**

Update count: **0**

Registration date

2018-10-20, 1397/07/28

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-22, 1396/06/31
Expected recruitment end date
 2018-10-22, 1397/07/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The efficacy of gluten free diet on clinical symptoms and signs, quality of life, and inflammatory factors in patients with irritable bowel syndrome under low FODMAP (Fermentable, Oligo-, Di-, Mono-saccharides And Polyols) diet

Public title
 Effect of gluten free diet in treatment of IBS

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 18-65 years Patients with irritable bowel syndrome, according to gastroenterologist diagnosed according to the ROME- IV criteria (1.Improvement with defecation
 2.Onset associated with a change in stool frequency
 3.Onset associated with a change in stool form (appearance) At least three days a month, three months a year and no pathological findings in the clinical investigating) lack of any organic intestinal disease(diagnosed by last 5 years ago colonoscopy) and intestinal infections(diagnosed by stool culture). No medical history of chronic gastrointestinal and colorectal disease Absence of any major bowel surgery Absence of regular use of laxatives or antidiarrheal drugs No chronic use of antibiotics, corticosteroids and immunosuppressants No usage of drugs that modifying the digestive motility such as metoclopramide, cisapride, diphenoxylylate,... No usage of drugs that increased bleeding of intestinal mucosa such as aspirin, warfarin, heparin,... No history of breast cancer in patient or in first-degree relatives of a person Absence of severe mental or behavioral disorder Absence of nicotine and its derivatives use in last 6 months No usage of NSAIDs and aspirin in last week(influence on gut permeability)
Exclusion criteria:

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

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **40**
 Actual sample size reached: **40**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The method use 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 three study groups according to the randomized distribution table.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

Velenjak St. , Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2017-10-15, 1396/07/23

Ethics committee reference number

IR.SBMU.RIGLD.REC.1396.154

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrom

ICD-10 code

k55-k64

ICD-10 code description

Other diseases of intestines

Primary outcomes

1

Description

Age

Timepoint

Beginning of study

Method of measurement

Question

2

Description

Gender

Timepoint

Beginning of study

Method of measurement

Observation

3

Description

Weight

Timepoint

Beginning and end of study

Method of measurement

Balance

4

Description

Height

Timepoint

Beginning and end of study

Method of measurement

Meter

5

Description

BMI

Timepoint

Beginning and end of study

Method of measurement

Calculation

Secondary outcomes

1

Description

Smoking

Timepoint

Beginning of study

Method of measurement

Question

2

Description

Type of diet

Timepoint

Beginning and end of study

Method of measurement

Data collection form

3

Description

Total Calorie Intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

4

Description

Total Carbohydrate Intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

5

Description

Total Protein Intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

6

Description

Total Fat Intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

7

Description

Total Fiber Intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

8

Description

Total MUFA Intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

9

Description

Total PUFA Intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

10

Description

Total SFA Intake

Timepoint

Beginning and end of the study

Method of measurement

Recall Questionare

11

Description

IL-6

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic method using a kit

12

Description

INF- γ

Timepoint

Beginning and end of the study

Method of measurement

Enzymatic method using a kit

Intervention groups

1

Description

Intervention group: 1) Group I: will receive food products with 8g/day gluten for first 2 weeks, 16g/day gluten for second 2 weeks, following 32g/day gluten for third 2 weeks.

Category

Treatment - Other

2

Description

Intervention group: 2) Group II: will continue low FODMAP+ strict (Gluten free) diet for 6 weeks.

Category

Treatment - Other

3

Description

Control group: will receive free diet for 6 weeks

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleqani Hospital

Full name of responsible person

Dr Mohammad Rostaminejad

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Afshin Zarghi

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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

Dr 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
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Azita Hekmatdoost
Position
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Latest degree
Master
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because the participant's informations should remain confidential.

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