Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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-ɣ

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)

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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, diphenoxylate,... 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

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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
Begining and end of the study
Method of measurement
Recall Questionare

4

Description
Total Carbohydrate Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

5

Description
Total Protein Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

6

Description
Total Fat Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

7

Description
Total Fiber Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

8

Description
Total MUFA Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

9

Description
Total PUFA Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

10

Description
Total SFA Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

11

Description
IL-6
Timepoint
Begining and end of the study
Method of measurement
Enzymatic method using a kit

12

Description
INF-ɣ
Timepoint
Begining 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
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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
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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 confidental.

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