Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of gluten free diet and regular diet on severity of clinical symptoms in patients with irritable bowel syndrome

Protocol summary

Study aim
Assessing the effect of gluten-free diet on clinical symptoms of patients with irritable bowel syndrome.

Design
A randomized, open label clinical trial on 44 patients. Groups include intervention and control groups. Patients will be randomly allocated to the groups using simple randomization method with random number table.

Settings and conduct
Participants will be selected from patients of Urmia Imam Khomeini gastrointestinal outpatient clinic and will be allocated randomly to the intervention and control groups. Demographic information and symptoms will be entered to checklist forms at the beginning of the study and patients symptoms will be reevaluated after 4 weeks. Because both patients and researchers are aware of diet type the study will be open labeled (not blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having Irritable bowel syndrome (IBS) according to ROME-IV diagnostic criterion; Having Irritable bowel syndrome (IBS) according to ROME-IV diagnostic criterion; Having informed consent and ability of participation in study and adherence to gluten free die; Being at least 18 years old. Non-inclusion criteria: Having inflammatory, infectious or organic gastrointestinal disease; Having coeliac disease.

Intervention groups
In intervention group gluten free diet will be prescribed and necessary information and education about the gluten free diet will be provided. In control group patients will continue their normal diet. All patients will receive standard treatment according to their symptoms.

Main outcome variables
Abdominal Pain; Constipation; Diarrhea; Abdominal Distention or Flatulence; Nausea and/or vomiting; Effect of disease on daily life; mental well-being; fecal urgency; incomplete defecation sense.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201204049599N1**
Registration date: **2021-02-13, 1399/11/25**
Registration timing: **retrospective**

Last update: **2021-02-13, 1399/11/25**
Update count: **0**

Registration date
2021-02-13, 1399/11/25

Registrant information

Name
Mohammad Reza Pashaee
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date
2020-01-21, 1398/11/01

Actual recruitment end date
2020-08-22, 1399/06/01

Trial completion date
2020-08-22, 1399/06/01

Scientific title

Comparison of the effect of gluten free diet and regular diet on severity of clinical symptoms in patients with irritable bowel syndrome

Public title
Effect of gluten free diet on irritable bowel syndrome symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having Irritable bowel syndrome (IBS) according to ROME-IV diagnostic criterion Having IBS Symptoms according to ROME-IV diagnostic criterion Having informed consent and ability of participation in study and adherence to gluten free diet Being at least 18 years old
Exclusion criteria:
Having inflammatory, infectious or organic gastrointestinal disease Having coeliac disease Having Cirrhosis Using corticosteroids, non steroidal anti-inflammatory drugs, or medications that are effective in gastrointestinal tract movement Having thyroid disease Pregnancy Psychiatric conditions and inability to give informed consent Being on gluten free diet before entering the study
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Actual sample size reached: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method is simple randomization. the researcher will divide patients by using table of random numbers. First, each patient will be assigned a two-digit code according to the date and time of the clinic visit. The first patient will have code 01 and the last patient will have code 44. Then in the table of random numbers without looking, a location will be randomly selected. The first two digits will be examined. If the number is less than or equal to 44, it will be selected, otherwise we will continue moving in the direction of the line and other numbers will be checked. If it is a duplicate number, it will be ignored and another number from the table will be checked. We continue this process until 22 codes are selected. The first 22 codes will be for patients in the intervention group (patients who will receive a gluten-free diet) and the remaining 22 codes will be for the control group (patients who will receive a normal diet). Thus, patients are randomly divided into two groups.
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 Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences; Resalat boulevard
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2019-12-18, 1398/09/27
Ethics committee reference number
IR.UMSU.REC.1398.348

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
Abdominal Distention or Flatulence
Timepoint
Before intervention and after 4 weeks
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Abdominal pain
Timepoint
Before intervention and after 4 weeks
Method of measurement
Visual Analogue Scale (VAS)

3

Description
Constipation
Timepoint
Before intervention and after 4 weeks
Method of measurement
Visual Analogue Scale (VAS)

4

Description
Diarrhea
Timepoint
Before intervention and after 4 weeks
Method of measurement
Visual Analogue Scale (VAS)

5

Description
Nausea and or vomiting
Timepoint
Before intervention and after 4 weeks
Method of measurement
Visual Analogue Scale (VAS)

6

Description
Disease effect on daily life
Timepoint
Before intervention and after 4 weeks
Method of measurement
Visual Analogue Scale (VAS)

7

Description
Mental well being
Timepoint
Before intervention and after 4 weeks
Method of measurement
Visual Analogue Scale (VAS)

8

Description
Fecal urgency
Timepoint
Before intervention and after 4 weeks
Method of measurement
According to patient history

9

Description
Incomplete defecation sense
Timepoint
Before intervention and after 4 weeks
Method of measurement
According to patient history

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Gluten free group. in this group necessary education about gluten free diet and foods that patients must avoid including wheat, barley and rye will be provided. At the beginning demographic information and symptoms will be documented. after 4 weeks patients will be reevaluated.
Category
Treatment - Other

2

Description
Control group: Normal Diet group. This group of patients will continue their normal diet with out any further intervention At the beginning demographic information and symptoms will be documented. after 4 weeks patients will be reevaluated.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mohammad Reza Pashaee
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Imam Khomeini Hospital; Ershad boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Mohammad Reza Pashaee
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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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
There is no more information provided.
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