Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between gluten-free regime and regime with gluten in symptoms of patients with IBS

Protocol summary

Study aim
A comparison of gluten free diet and gluten containing diet hn patties with IBS
Design
The study is a clinical trial performed 140 people and to intervention and control groups
Settings and conduct
The study was conducted on population referred to the gastroenterology clinic of Imam Khomeini hospital in Ahvaz; these patents were first evaluated by Rome 3 questionnaire and voluntarily entered the study. individuals were needed on give diet for 12 weeks and after completing the intervention and the interval of 4 weeks; the intervention was competed by the resercher's assistance
Participants/Inclusion and exclusion criteria
All patients with IBS referred to the imam khomeini clinic were qualified to be studied. and those who weren't qualified to be studied such as; pregnancy or breastfeeding; the history of abdominal surgery; patients with opioid use; non-steroidal anti-inflammatory; long-term antibiotic drug consumption; kideny failure; the presence of serious physical illnesses; celiac disease; diabetes; organogenesis of the digestive system based onn doing endoscopy and colonoscopy test; fail to adherence to gluten-free diet during patient studies
Intervention groups
A group was faded gluten-free diet and on gluten-containing diet to measure IBS symptoms
Main outcome variables
Frequency of abdominal detention; frequent feeling of pain or abdominal discomfort; frequency of diarrhea and constipation; the number of times you push too hard while defecating; frequent feeling of pain abdominal discomfort after eating; the number of times abdominal pain keeps you from sleeping or wake you up at night; the number of times an individual has urgently needed to go to a toilet for defecation within the last 12 weeks

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20110816007350N2**
Registration date: **2019-04-30, 1398/02/10**
Registration timing: **retrospective**

Last update: **2019-04-30, 1398/02/10**
Update count: **0**
Registration date
2019-04-30, 1398/02/10

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2014-06-22, 1393/04/01
Expected recruitment end date
2014-12-31, 1393/10/10
Actual recruitment start date
2014-06-22, 1393/04/01
Actual recruitment end date
2014-12-31, 1393/10/10
Trial completion date
2014-12-31, 1393/10/10

Scientific title
Comparison between gluten-free regime and regime with gluten in symptoms of patients with IBS

Public title
The effect of a gluten free diet and a diet which contain gluten on the treatment of IBS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with IBS referring to Gastroenterology Clinic of Imam Khomeini Hospital
Exclusion criteria:
Pregnancy or breastfeeding The history of abdominal surgery Patients with opioid use Non-steroidal anti-inflammatory Long-term antibiotic drug consumption Kidney Failure The presence of serious physical illnesses Celiac disease Diabetes Organogenesis of the digestive system based on doing endoscopy and colonoscopy test Fail to adherence to gluten-free diet during patient studies
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **140**
Actual sample size reached: **140**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Ahvaz University of medical sciences
Street address
No.4/111, Ramtin dead end, First Apadana Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81065646433
Approval date
2014-05-10, 1393/02/20
Ethics committee reference number
ajums.ac.ir.1393.64

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome
ICD-10 code
K58.0
ICD-10 code description
Irritable bowel syndrome with diarrhea

Primary outcomes

1

Description
Abdominal pain
Timepoint
Patients were first assessed by Rome 3 questionnaire and weeks after the end of the treatment period based period based on symptoms they were graded from 0-3
Method of measurement
Likert scale

2

Description
gas bowel
Timepoint
Patients were first assessed by Rome 3 questionnaire and weeks after the end of the treatment period based period based on symptoms they were graded from 0-3
Method of measurement
Likert scale

3

Description
Reduce the frequency of defecation
Timepoint
Patients were first assessed by Rome 3 questionnaire and weeks after the end of the treatment period based period based on symptoms they were graded from 0-3
Method of measurement
Likert scale

4

Description
Increase the frequency of defecation
Timepoint
Patients were first assessed by Rome 3 questionnaire and weeks after the end of the treatment period based

period based on symptoms they were graded from 0-3

Method of measurement

Likert scale

5

Description

Diarrhea

Timepoint

Patients were first assessed by Rome 3 questionnaire and weeks after the end of the treatment period based period based on symptoms they were graded from 0-3

Method of measurement

Likert scale

6

Description

Constipation

Timepoint

Patients were first assessed by Rome 3 questionnaire and weeks after the end of the treatment period based period based on symptoms they were graded from 0-3

Method of measurement

Likert scale

Secondary outcomes

1

Description

Incomplete evacuation of stools

Timepoint

Patients were first assessed by Rome 3 questionnaire and weeks after the end of the treatment period based period based on symptoms they were graded from 0-3

Method of measurement

Likert scale

Intervention groups

1

Description

Intervention group: In order to use the gluten free diet, the intervention group received a list of gluten free foods along with addressees of the stores which sell and distribute these foods. Individuals were fed on given diet for 12 weeks. After describing the importance of the study, the intervention group was asked to fill in the correct diet checklist and given it to the researcher at the end of the intervention. Post-test was completed after finishing the intervention and considering the interval of 4 weeks of intervention by the researcher's assistance. Samples were also followed up with both groups until the end of the intervention.

Category

Treatment - Other

2

Description

Control group: The control group received an ordinary diet for 12 weeks. Patients were evacuated on signs such as pain intensity, pain duration, frequency of defecation and bloating.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital medical University Ahvaz

Full name of responsible person

Dr.Eskandar Hajiani

Street address

No.4/111, Ramtin dead end, First Apadana Street, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Eskandar Hajiani

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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

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Sina Babazadeh
Position
Doctor Super specialty
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterology
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Person responsible for scientific inquiries

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Full name of responsible person
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Latest degree
Subspecialist
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Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Sina babazadeh
Position
Doctor Super specialty
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterology
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable