

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

Name

sina babazadeh

Name of organization / entity

ahvaz jundishapur university of medical sciences

Country

Iran (Islamic Republic of)

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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

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

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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

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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

Isfahan

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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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Latest degree

Subspecialist

Other areas of specialty/work

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City**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