Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of gastrointestinal symptoms use of gluten and gluten free diet in Irritable Bowel Syndrom patients referred to gastrointestinal clinic at Imam Khomeini Hospital during 2012

Protocol summary

Summary

Disease control is done with care and support psychological and diets. Several studies have shown that patients with irritable bowel syndrome with gluten-free diet have been well controlled. In contrast, in some studies, the placebo response rate was similar to the gluten free diet. Due to the growing irritable bowel syndrome, gluten unknown effects on the release of gastrointestinal symptoms, this study is a comparative study of a gluten-free diet on gastrointestinal symptoms in patients with irritable bowel syndrome have been implemented. In a clinical trial conducted during 2012 and 2013 in Tehran's Imam Khomeini Hospital, 72 patients (35 patients in gluten group and 37 patients in placebo group) enter the study. In the first step the patients receive the gluten-free diet for six weeks using a standard visual analog scale (VAS), clinical symptoms include bloating, abdominal pain, satisfaction with stool consistency, nausea, tiredness, patients are asked. At 6 weeks, patients whose symptoms improved to an acceptable level and gluten-free diet is effective in terms of disease, in the second stage are randomly divided into two groups. The first group of packages containing powdered gluten (gluten) and the second group of packages containing powdered food containing gluten (placebo) was given. At the end of each week , the severity of patients' symptoms are evaluated according to VAS criteria till 6 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071413996N1**
Registration date: **2013-08-29, 1392/06/07**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-08-29, 1392/06/07

Registrant information

Name
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Name of organization / entity
tehran university of medical sciences
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Recruitment status

Recruitment complete

Funding source

Digestive Disease Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2012-10-12, 1391/07/21

Expected recruitment end date

2013-05-20, 1392/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of gastrointestinal symptoms use of gluten and gluten free diet in Irritable Bowel Syndrom patients referred to gastrointestinal clinic at Imam Khomeini Hospital during 2012

Public title
Effect of gluten diet in Irrtable Bowel Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
The study population consist of having IBS based on Rome III diagnostic criteria . Inclusion criteria for the study subjects are: IBS according to Rome III diagnostic criteria of having; age more than 16 years; with informed consent regarding participation in the research project. Exclusion criteria include patients who do not consent to participate in the study; symptoms of gluten-free diet in the first phase of the study; serum Anti TTG positive test; Celiac disease; Pathologic positive CD (Marsh greater than zero) that in patient who (because of positive tests for each of the HLA-DQ2, HLA-DQ8; anti Gliadin Ab (IgG), (IgA) anti Gliadin Ab) underwent endoscopic duodenal biopsy specimens is taken; inflammatory bowel disease; Depression; diabetes; alcohol abuse; none steroidal anti-inflammatory drugs; abnormal levels of glucose; urea; creatinine; sodium; potassium; hemoglobin; ESR and thyroid functional tests.
Age
From **16 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Digestive Disease Resaerch Center
Street address
Dr.Shariati hospital, Kargar-shomali Street
City
Tehran
Postal code
1411713135
Approval date
2012-10-11, 1391/07/20
Ethics committee reference number
416/991

Health conditions studied

1

Description of health condition studied
Irritable Bowel Syndrome
ICD-10 code
k58
ICD-10 code description
Irritable Bowel Syndrome with Diarrhea

Primary outcomes

1

Description
Feeling gas in stomach
Timepoint
BeforE intervention, at the end of the first week till 6th week
Method of measurement
VAS

2

Description
Abdominal pain
Timepoint
Before intervention, at the end of the first week till 6th week
Method of measurement
VAS

3

Description
Defecation satisfaction
Timepoint
Before intervention, at the end of the first week till 6th week
Method of measurement
VAS

4

Description
Nausea
Timepoint
Before intervention, at the end of the first week till 6th week
Method of measurement
VAS

Secondary outcomes

1

Description

Fatigue

Timepoint

Before intervention and at the end of 6th week

Method of measurement

VAS

Intervention groups

1

Description

The gluten group is given a packet containing gluten meal (free of fermentable oligo di-monosaccharides and polyols and proteins including 2.3% non-gluten, 45% gluten , 52% gliadin and 27.7 gr glucose) .Patients consume powder for 6 weeks, while both groups continue gluten-free diet. Packages containing 2 pack of 50 grams powder which should be poured in a cup containing 150 ml of warm water , then stirring the emulsion immediately and consumed with breakfast and dinner .

Category

Treatment - Drugs

2

Description

The placebo group is given packets containing powder of gluten-free foods (plain flour, corn starch and glucose). Patients consume powder for 6 weeks, while both groups continue gluten-free diet. Packages containing 2 pack of 50 grams powder which should be poured in a cup containing 150 ml of warm water , then stirring the emulsion immediately and consumed with breakfast and dinner .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Amir Saeed Sadeghi

Street address

Imam Khomeini Hospital , keshavarz bulevard

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Digestive Disease Resaerch Center

Full name of responsible person

Reza Malekzade

Street address

Dr.Shariati hospital, Kargar-shomali Street

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Digestive Disease Resaerch Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Imam Khomeini Hospital

Full name of responsible person

Amir Saeed Sadeghi

Position

Fellow of Gastroenterology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam Khomeini Hospital

Full name of responsible person

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Position

Associate Professor of Gastroenterology

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty