Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The efficacy of synbiotic supplements containing Bacillus coagulans and inulin with low FODMAP diet compared with low FODMAP diet alone on inflammatory factors, clinical outcomes and quality of life in patients with irritable bowel syndrome

Protocol summary

Study aim

To investigate the efficacy of synbiotic supplements containing Bacillus coagulans and inulin with low FODMAP diet compared with low FODMAP diet alone on inflammatory factors, clinical outcomes and quality of life in patients with irritable bowel syndrome.

Design

Randomized Clinical Trial double blind

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. Patients were randomized to receive a synbiotic containing Bacillus coagulans plus low FODMAP diet or low FODMAP diet (and placebo) for 8 weeks. Before and after the intervention blood and fecal samples will be collected 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

Intervention group: will receive one synbiotic capsule containing Bacillus coagulans(0.1) g and inulin(0.9 g) per day plus low FODMAP diet for 8 weeks Control: will receive low FODMAP diet and placebo for 8 weeks

Main outcome variables

Abdominal pain intensity, Abdominal pain frequency, Abdominal distension, Satisfaction with bowel habits, Interference with community function, Defecation frequency, Defecation consistency, Patient-rated Severity score, serum level of IL-6 and INF-ɣ

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N27**
Registration date: **2018-12-13, 1397/09/22**
Registration timing: **retrospective**

Last update: **2018-12-13, 1397/09/22**
Update count: **0**

Registration date

2018-12-13, 1397/09/22

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences, National Institute of Nutrition Research

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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 synbiotic supplements containing Bacillus coagulans and inulin with low FODMAP diet compared with low FODMAP diet alone on inflammatory factors, clinical outcomes and quality of life in patients with irritable bowel syndrome

Public title

Effect of Bacillus coagulans and inulin compared with low FODMAP 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 monthsNo usage of NSAIDs and aspirin in last week(influence on gut permeability)

Exclusion criteria:

Life threatening symptoms Death Not agree to continue the study

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: **50**

Actual sample size reached: **50**

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 2 study groups according to the randomized distribution table.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Research Institute, Shahid Beheshti University of Medical Sci

Street address

West arghavan, Sanaat square, Farahzadi boulvard, Shahrake gharb

City

Tehran

Province

Tehran

Postal code

193954741

Approval date

2017-12-31, 1396/10/10

Ethics committee reference number

IR.SBMU.nnftri.Rec.1396.206

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrom

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Abdominal pain intensity

Timepoint

Beginning and end of study

Method of measurement

Questionaire

2

Description
Abdominal pain frequency
Timepoint
Beginning and end of study
Method of measurement
Questionaire

3

Description
Abdominal distension
Timepoint
Beginning and end of study
Method of measurement
Questionaire

4

Description
Satisfaction with bowel habits
Timepoint
Beginning and end of study
Method of measurement
Questionaire

5

Description
Interference with community function
Timepoint
Beginning and end of study
Method of measurement
Questionaire

6

Description
Defecation frequency
Timepoint
Beginning and end of study
Method of measurement
Questionaire

7

Description
Defecation consistency
Timepoint
Beginning and end of study
Method of measurement
Questionaire

Secondary outcomes

1

Description
Patient-rated Severity score
Timepoint
Begining and end of the study
Method of measurement
Questionare

2

Description
IBS-SSS
Timepoint
Begining and end of the study
Method of measurement
Questionare

3

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

4

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

Intervention groups

1

Description
Intervention group: will receive one synbiotic capsule containing Bacillus coagulans(0.1) g and inulin(0.9 g) per day plus low FODMAP diet for 8 weeks
Category
Treatment - Other

2

Description
Control group: will receive low FODMAP diet and placebo (starch) for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleqani Hospital
Full name of responsible person
Amir Sadeghi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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