Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of supplementation with a multi-species probiotic formulation (BioIBS®) on severity of symptoms and quality of life in patients with irritable bowel syndrome

Protocol summary

Study aim

Effects of supplementation with a multi-species probiotic formulation (BioIBS®) on severity of symptoms and quality of life in patients with irritable bowel syndrome

Design

Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer generated random numbers. 60 patients with IBS of eligible in the study will be selected. Patients will be assigned to receive either probiotic supplements and placebo.

Settings and conduct

This study is performed on patients with IBS referred to the gastroenterology clinic of Ayatollah Taleghani Hospital.This randomized,double-blind, placebo-controlled trial will be performed among IBS patients.Patients will be randomly divided into two groups of 30 people (probiotic supplement and placebo). Fecal and blood samples will be collected from patients at the baseline and end of the study so that the sample population and the researchers are not aware of the capsules nature of each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages range of 18-75 years, presence of Rome IV diagnostic criteria for IBS ؛ Hb < 10 g/dl. Exclusion criteria: surgical resection of the stomach,small intestine or large intestine,inflammatory bowel disease and ischemic colitis,infectious enteritis,hyperthyroidism or hypothyroidism,Pregnancy,used an over the counter or prescription laxative medication and probiotic or an antibiotic within 4 weeks prior to screening.

Intervention groups

probiotic capsule: containing L. rhamnosus, L. casei, L. acidophilus ؛placebo capsule: containing magnesium stearate and lactose

Main outcome variables

composition of the gut microbiota, blood biomarkers including cytokines (INF-γ, IL-6 and IL-10) and oxidative stress (Malondialdehyde (MDA) and total antioxidant capacity (TAC), severity of symptoms, improvement or worsening, and quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200915048727N1**
Registration date: **2020-10-16, 1399/07/25**
Registration timing: **prospective**

Last update: **2020-10-16, 1399/07/25**
Update count: **0**

Registration date

2020-10-16, 1399/07/25

Registrant information

Name

Abbas Yadegar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2518

Email address

a.yadegar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of supplementation with a multi-species probiotic formulation (BioIBS®) on severity of symptoms and quality of life in patients with irritable bowel syndrome

Public title

Effect of probiotic in irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of Rome IV diagnostic criteria for IBS male and female subjects in age range of 18-75 years.

Exclusion criteria:

Anemic subjects with Hb < 10 g/dl. Subjects with organic disease (to be ruled out by physician based on prior history and physical examination). Subjects with a history of surgical resection of the stomach, small intestine or large intestine. Subjects with a history of or complications from inflammatory bowel disease (Crohn's disease or ulcerative colitis) and ischemic colitis. Subjects with complications from infectious enteritis, hyperthyroidism or hypothyroidism. Subjects with a history of any diet-based intolerance (gluten or lactose intolerance). Subjects who are pregnant or planning on becoming pregnant throughout the course of the study. Subjects with uncontrolled Type II diabetes mellitus. Subjects who are immuno-compromised Subjects who have used an over-the-counter or prescription laxative medication or any other herbal agents affecting GI motility within 2 weeks prior to screening. Subjects who have used probiotic or fiber supplements (or probiotic/fiber enriched foods) or an antibiotic within 4 weeks prior to screening. Subjects who have used IBS specific treatments within 4 weeks prior to screening. Subjects who have participated in a clinical research trial within 30 days prior to randomization.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will occur centrally using an phone randomization system by an independent researcher. There are two treatment arms.Randomization in the mentioned groups will be conducted according to permuted block randomization based on basis of 4 and 6 blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Probiotic and placebo capsules will be provided by Tak Gene Zist. Probiotic and placebo capsules in boxes numbered according to randomization sequence for each group of patients will be provided by Tak Gene Zist. Probiotic and placebos capsules will be packed in similar boxes, and researchers and patients will not know the contents of the packages until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak Ave,Taleghani Hospital,Tehran

City

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Province

Tehran

Postal code

1985714711

Approval date

2020-10-05, 1399/07/14

Ethics committee reference number

IR.SBMU.RIGLD.REC.1399.045

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome (IBS)

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description
Changes in severity of IBS symptoms (IBS-SSS)
Timepoint
At baseline, 4 and the 8 weeks after the intervention
Method of measurement
Questionnaire (IBS, Symptom Severity Scoring)

2

Description
quality of life
Timepoint
At baseline,4 and the 8 weeks after the intervention
Method of measurement
IBS-QOL-34

3

Description
Adequate Relief
Timepoint
At baseline,4 and the 8 weeks after the intervention
Method of measurement
IBS, Adequate Relief (IBS, AR)

4

Description
Improvement or worsening of IBS global symptoms (IBS-GIS)
Timepoint
At baseline, 4 and the 8 weeks after the intervention
Method of measurement
Global Improvement Scale (IBS-GIS)

Secondary outcomes

1

Description
Malondialdehyde (MDA)
Timepoint
At baseline, and the 8 weeks after the intervention
Method of measurement
Thiobarbituric Acid assay

2

Description
Total antioxidant capacity (TAC)
Timepoint
At baseline, and the 8 weeks after the intervention
Method of measurement
Colorimetric method

3

Description
IL-6
Timepoint
At baseline, and the 8 weeks after the intervention
Method of measurement
ELISA

4

Description
INF-ɣ
Timepoint
At baseline, and the 8 weeks after the intervention
Method of measurement
ELISA

5

Description
IL-10
Timepoint
At baseline, and the 8 weeks after the intervention
Method of measurement
ELISA

6

Description
gut microbiom
Timepoint
At baseline, and the 8 weeks after the intervention
Method of measurement
Real-time PCR (qPCR) assay

Intervention groups

1

Description
Intervention group: : probiotic capsule (Bio IBS®, Takgene zist , Iran) containing L. rhamnosus, L. casei, L. acidophilus. Each capsule containing 5×109 cfu⁄capsule. 2 capsules per day, Duration 2 months.
Category
Treatment - Drugs

2

Description
Control group: placebo capsule (Takgene zist, Iran). 2 capsules per day, Duration 2 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
taleghani hospital
Full name of responsible person
dr Amir Sadeghi
Street address
shahid arabi st, yaman st, shahid chamran Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
dr hamid assadzade
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Takgene zist
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Person responsible for updating data

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shirin.hajyani65@gmail.com

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
Patient information is kept confidential and will not be published
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
No - There is not 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
No - There is not a plan to make this available