Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Effect of multispecies probiotic supplementation on Irritable bowel syndrome

Protocol summary

Study aim
To investigate the effect of multispecies probiotic supplementation on various aspects of IBS in order to confirm, modify or reject the results of previous studies in this field

Design
Randomized Placebo-controlled Double Blind with parallel group clinical trial Study phase: 3 Blocked randomization Estimated sample size: 50, 25 in the intervention group and 25 in the control group

Settings and conduct
Samples will be selected from among the referrals to the gastroenterology clinic of Ayatullah Golpayegani Qom Hospital.Packages of products will be encoded in two types by the company. The codes are kept secret from patients and researchers, and will be announced to the researchers after the completion of the RCT.

Participants/Inclusion and exclusion criteria
Inclusion criteria before randomization: 1.The Rome II criteria;2.Age over 18 years;3.The informed consent Exclusion criteria before randomization: 1.Hx of major GI surgery;2.Chronic use of antibiotics, corticosteroids & immunosuppressive drugs;3.Regular use of drugs that alter GI movements;4.Severe psychological and behavioral disorders;5.Food allergy;6.Hx of any organic bowel disease or chronic digestive illness Exclusion criteria after randomization: 1.Onset of any acute GI disease during the study;2.A major change in the diet or lifestyle of the patient during study;3 Incidence of any side effects due to taking drugs;4.Unwillingness or inability of the patient to continue the collaboration

Intervention groups
Intervention group: Patients will receive Familact® probiotic capsules. Control group: Patients will receive placebo capsules.

Main outcome variables
1.Type of the IBS 2.Severity of abdominal pain 3.Amount of abdominal discomfort 4.Amount of bloating and/or abdominal swelling 5.Heartburn 6.Nausea 7.The bowel habits than before the treatment 8.Improvement of overall IBS symptoms 9.Quality of patients' lives

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181231042191N1**
Registration date: **2019-04-18, 1398/01/29**
Registration timing: **prospective**

Last update: **2019-04-18, 1398/01/29**
Update count: **0**

Registration date
2019-04-18, 1398/01/29

Registrant information
Name
Mersad Amery
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-04-20, 1398/01/31
Expected recruitment end date
2019-06-05, 1398/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of multispecies probiotic supplementation on Irritable bowel syndrome

Public title
probiotics in Irritable bowel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients will be selected based on the Rome II criteria according to the gastroenterologist diagnosis ; (Rome II criteria: abdominal pain or any digestive discomfort for at least 3 months during the last year that can be consecutive or non-consecutive, along with two of the three following items: relieving pain by defecation, starting symptoms associated with change in the frequency of bowel movements, starting symptoms associated with change in the shape of feces) Age of at least 18 years old The informed consent of the patient, which is submitted in writing form after all necessary explanations are given to him/her.

Exclusion criteria:
History of major gastrointestinal surgery chronic use of antibiotics, corticosteroids and immunosuppressive drugs Regular use of drugs that alter gastrointestinal movements such as metoclopramide, cisapride, domperidone, narcotics especially opioid derivatives, laxatives, anti-diarrheal agents, as well as other effective drugs for the treatment of IBS, as described in more detail in the text. Presence of severe psychological and behavioral disorders in the patient Food allergy History of any organic bowel disease or chronic digestive illness

Age
From **18 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: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The following clinical trial will be Double Blind Randomized Placebo-controlled. In this clinical trial study, the sample size is estimated to be 50, which will eventually be 25 in the intervention group and 25 in the control group. Samples will be selected from among the referrals to the gastroenterology clinic of Ayatullah Golpayegani Qom Hospital.Packages of products will be encoded in two types by the company; a code for the original drug and a code for the placebo. Each of the two groups that are randomly assigned will receive a type of drug code. The codes are kept secret from patients and researchers, and will be announced to the researchers at the end of the study after the completion of the clinical trial.

Blinding (investigator's opinion)
Double blinded

Blinding description
The following clinical trial will be Double Blind Randomized Placebo-controlled. In this clinical trial study, the sample size is estimated to be 50, which will eventually be 25 in the intervention group and 25 in the control group. Blocked randomization method is considered for this study. In this way, the first eligible patient is assigned to the Group A and the second one to the Group B, and so the rest of the patients are divided between the two groups one after the another.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University of Qom

Street address
Medical College, 15 Khordad Blvd

City
Qom

Province
Ghoum

Postal code
3749113191

Approval date
2018-11-06, 1397/08/15

Ethics committee reference number
IR.IAU.QOM.REC.1397.042

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome

ICD-10 code
K58

ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Severity of abdominal pain: discrete quantitative dependent variable
Timepoint
At the beginning of the study (before the intervention) and at the end of the study (end of the intervention)
Method of measurement
The questionnaire (numbers from 0 to 10 to assess the severity of the abdominal pain; zero indicates no pain and 10 indicates pain is very severe)

2

Description
Amount of abdominal discomfort: discrete quantitative dependent variable
Timepoint
At the beginning of the study (before the intervention) and at the end of the study (end of the intervention)
Method of measurement
The questionnaire (numbers from 0 to 10 to assess the amount of the abdominal discomfort; zero indicates no discomfort and 10 indicates very severe discomfort)

3

Description
Amount of bloating and/or abdominal swelling: discrete quantitative dependent variable
Timepoint
At the beginning of the study (before the intervention) and at the end of the study (end of the intervention)
Method of measurement
The questionnaire (numbers from 0 to 10 to assess the amount of the bloating and/or abdominal swelling; zero indicates no bloating and/or abdominal swelling and 10 indicates bloating and/or abdominal swelling is very severe)

4

Description
Heartburn: Nominal qualitative dependent variable
Timepoint
At the beginning of the study (before the intervention) and at the end of the study (end of the intervention)
Method of measurement
Questionnaire (has / not)

5

Description
Nausea: Nominal qualitative dependent variable
Timepoint
At the beginning of the study (before the intervention) and at the end of the study (end of the intervention)
Method of measurement
Questionnaire (has / not)

6

Description
The bowel habits (in terms of frequency of defecation and stool consistency) than before the onset of treatment: Nominal qualitative dependent variable
Timepoint
At the end of the study (end of the intervention)
Method of measurement
Questionnaire (worse / no change / better)

7

Description
Improvement of overall IBS symptoms than before starting the treatment: Nominal qualitative dependent variable
Timepoint
At the end of the study (end of the intervention)
Method of measurement
Questionnaire (Yes / No)

8

Description
Quality of patients' lives: Nominal qualitative dependent variable
Timepoint
At the beginning of the study (before the intervention) and at the end of the study (end of the intervention)
Method of measurement
IBS-QOL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive two 500 mg Familact® probiotic capsules, produced by Tehran Zisttakhmir Company, daily for 30 consecutive days. To maximize absorption, the time of medication taking will recommended between each meal. The count of the Familact production is {10}^9 CFU and contains Lactobacillus casei، Lactobacillus acidophilus، Lactobacillus rhamnosus، Lactobacillus bulgaricus ،Bifidobacterium breve، Bifidobacterium longum، Streptococcus thermophilus and Fructooligosaccharides (FOS).
Category
Treatment - Drugs

2

Description
Control group: Patients will receive two 500 mg placebo capsules daily for 30 consecutive days. Capsules contain an inert substance that are designed and manufactured with the same appearance and packaging as the original

and unidentifiable for the patients and researchers by the company(Tehran Zisttakhmir Company). As it is indistinguishable with the original drug, the time of medication taking will recommended just similar to the original drug, between each meal.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Golpaygani hospital

Full name of responsible person
Mersad Amery

Street address
Ayatollah Golpayegani Hospital, Molavi Ave.

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Qom

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mahboube Sadat Sharif

Street address
Qom Azad University, Daneshgah Blvd., Pardisan town

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Phone
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info@qom-iau.ac.ir

Web page address
http://www.qom-iau.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mersad Amery

Position
Medical Intern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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No. 15, 29 Ave.,15 Khordad Blvd

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Person responsible for scientific inquiries

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Full name of responsible person
Mersad Amery

Position
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Latest degree
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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Yes - There is 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
Not applicable

Title and more details about the data/document
SPSS data file with unidentifiable personal data will be available for applicant researchers, after completion and publication of this study

When the data will become available and for how long
Start the access period after official publication of the results

To whom data/document is available
Both researchers and related industries

Under which criteria data/document could be used
Any kind of scientific, practical and research use by informing and obtaining consent from researchers is allowed.

From where data/document is obtainable
refer to project researchers Email address: mersadamery@yahoo.com

What processes are involved for a request to access data/document
By sending a request in the email; providing the full details of identification including name and membership number in the scientific, research or industrial reference, and a full explanation of the type of use of the data and their goals.

Comments