

# 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)

##### Phone

+98 23 3422 7387

##### Email address

mersadamery@yahoo.com

##### 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**

Ghous

**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 be 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 Zistakhmir 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.

**City**

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**Province**

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**Postal code**

3719618990

**Phone**

+98 25 3616 1111

**Email**

h.golpayegani@gmail.com

**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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**Province**

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**Postal code**

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**Phone**

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**Email**

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

**Street address**

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**Province**

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**Postal code**

3714685644

**Phone**

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**Email**

mersadamery@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mersad Amery

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mersad Amery

**Position**

Medical Intern

**Latest degree**

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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**