Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effectiveness of adding probiotic / prebiotic combination to the usual treatment on the severity of depressive symptoms and irritable bowel syndrome

Protocol summary

Study aim
Determining and comparing the effectiveness of probiotic/prebiotic combination on the severity of depressive symptoms and irritable bowel syndrome

Design
The randomized, double-blind clinical trial, with the parallel groups, Phase 3 on 48 patients

Settings and conduct
In this randomized double-blind clinical trial study, 48 eligible patients referred to the gastroenterology and psychiatry clinic of Al-Zahra hospital of Isfahan will be included in the study and will be randomly divided into 2 groups. Patients in the control group will be given the usual treatment, and in the intervention group, a probiotic/prebiotic combination will be prescribed. The patient and the researcher will have no knowledge of the type of intervention and the conditions were double-blind. Then the symptoms of depression and IBS of patients will be compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria included age 18 to 65 years, diagnosis of moderate to severe IBS, minimum literacy, no depressive disorders, bipolar disorder or psychotic disorders, no suicide plan or serious thoughts at the time of enrollment, no pregnancy or breastfeeding, no history of any bowel surgery, no drug use From the onset of symptoms and consent to participate in the study. Exclusion criteria include the diagnosis of any organic disease during the study, non-cooperation in the use of drugs regularly, and the occurrence of any side effects, including allergic and gastrointestinal complications.

Intervention groups
Intervention group: For patients in this group, in addition to the usual treatment, the probiotic/prebiotic combination is given as one capsule daily for 12 weeks. Control group: For patients in this group, only the usual treatment is used.

Main outcome variables
Depression, Anxiety, Stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190404043159N5**
Registration date: **2021-12-13, 1400/09/22**
Registration timing: **prospective**

Last update: **2021-12-13, 1400/09/22**
Update count: **0**

Registration date
2021-12-13, 1400/09/22

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of adding probiotic / prebiotic combination to the usual treatment on the severity of depressive symptoms and irritable bowel syndrome

Public title

Evaluation of the effectiveness of probiotic/prebiotic on the severity of depressive symptoms and irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years Diagnosis of moderate to severe IBS based on ROME III criteria Have a minimum literacy Absence of Depressive Disorders, Bipolar Disorders or Psychotic Disorders Based on DSM-V Diagnostic Criteria by Psychiatrist and Psychiatric Assistant No suicidal plans or thoughts at the time of enrollment Do not take antidepressants and anti-anxiety drugs at the time of enrollment until 2 weeks before No pregnancy or breastfeeding No history of any bowel surgery Do not use drugs since the onset of symptoms Satisfaction to participate in the study

Exclusion criteria:

Diagnosis of any organic disease during the study Lack of cooperation in taking medications regularly Causes any side effects, including allergic and gastrointestinal side effects

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 48 eligible patients are randomly selected. For this, the letter A is written on 24 sheets, and the letter B is written on 24 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to observe blindness, the drugs are prepared in the same shape and amount before the intervention and are coded and given to the physician. They prescribe them without knowing the type of each drug. Therefore, the patient, the patient, the person recording the clinical and baseline information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan university of Medical sciences

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfehan

Postal code

۸۱۳۷۸۶۶۵۱۵

Approval date

2021-09-27, 1400/07/05

Ethics committee reference number

IR.MUI.MED.REC.1400.510

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

Symptoms of Irritable Bowel Syndrome

Timepoint

Before intervention, 6 and 12 weeks after intervention

Method of measurement

Questionnaire the irritable bowel severity scoring system (IBSSS)

Secondary outcomes

1

Description
Depression
Timepoint
Before intervention, 6 and 12 weeks after intervention
Method of measurement
Questionnaire of Depression, Anxiety and Stress Scale (DASS)

2

Description
Anxiety
Timepoint
Before intervention, 6 and 12 weeks after intervention
Method of measurement
Questionnaire of Depression, Anxiety and Stress Scale (DASS)

3

Description
Stress
Timepoint
Before intervention, 6 and 12 weeks after intervention
Method of measurement
Questionnaire of Depression, Anxiety and Stress Scale (DASS)

Intervention groups

1

Description
Intervention group 1: For patients in this group, in addition to the usual treatment, the probiotic/prebiotic combination of familact 2 Plus (which contains eight bacterial strains and the prebiotic fructooligosaccharide) is given as one capsule daily for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: For patients in this group, only the usual treatment is used and capsules containing corn starch (as a placebo) similar to the intervention group will be prescribed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospial
Full name of responsible person
Mohammad Reza Sharbafchi
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Department of Psychiatry, Al-Zahra Hospital, Hezar Jarib Street.
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Sponsors / Funding sources

1

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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
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Reza Sharbafchi
Position

Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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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
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available