Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation and comparison of the therapeutic effects of probiotics, Bismuth subsalicylate and placebo in patients with abdominal bloating in patients referring to gastrointestinal clinic in Khorshid hospital.

Protocol summary

Study aim
Evaluation and comparison of the therapeutic effect of probiotics, bismuth subsalciate and placebo in patients with abdominal bloating

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 100 patients. The random number table function was used to randomize.

Settings and conduct
The present study will be performed as a clinical intervention in the gastrointestinal clinic of Khorshid Hospital in Isfahan. Patients will be randomized and divided into 3 groups. Patients, researchers, and evaluators will not know about the groups and received medications . Patients will be treated according to their group for 8 weeks. Patients' symptoms are measured by the bloating intensity questionnaire as well as the IBS-QOL questionnaire.

Participants/Inclusion and exclusion criteria
In this study, all patients with bloating enter. Inclusion criteria include: 1. Age between 20 and 50 years 2. Having functional abdominal bloating based on Rome III criteria 3. Feeling bloated for at least 3 days a month for the last 3 months Exclusion criteria: 1. Any history of chronic inflammatory disease or structural gastrointestinal disease 2. Any serious physical illness or illness, such as inflammation or malignancy 3. Abnormal experiments 4. Use of calcium channel blockers in the last 3 months 5. Severe stress in the last 6 months

Intervention groups
Group 1 receive Familact probiotic tablets by Zist-tskhmir company containing 7 bacterial strains (Lactobacilli, Bifidobacteria, Streptococcus thermophilus) every 12 hours after the main meal. Group 2 Bismuth Subsalicylate Pills will receive 120 mg every 12 hours after a meal. Group 3 will also receive placebo tablets containing starch in the same way every 12 hours. The duration of treatment is 8 weeks.

Main outcome variables
Abdominal bloating

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200601047621N1**
Registration date: **2020-06-18, 1399/03/29**
Registration timing: **prospective**

Last update: **2020-06-18, 1399/03/29**
Update count: **0**

Registration date
2020-06-18, 1399/03/29

Registrant information

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Maryam Soheilipour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-29, 1399/05/08

Expected recruitment end date
2020-11-03, 1399/08/13

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation and comparison of the therapeutic effects of probiotics, Bismuth subsalicylate and placebo in patients with abdominal bloating in patients referring to gastrointestinal clinic in Khorshid hospital.

Public title
Probiotics Bismuth Subsalicylate and Abdominal Bloating
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All of the Patients with Abdominal Bloating Age between 20 and 50 years Feeling bloated for at least 3 days a month for the last 3 months The first experience of bloating more than 6 months ago
Exclusion criteria:
Any history of chronic inflammatory disease or structural disease of the gastrointestinal tract Any serious physical problems or illness, such as inflammation or malignancy Use of calcium channel blockers in the last 3 months Severe stress in the last 6 months Positive family history for Colon Concert History of inflammatory diseases Lactase deficiency disease Celiac disease
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (for example, top or bottom) and the researcher's second default is to consider numbers 0-33 for group 1, numbers 34-66 for group 2, and numbers 67-99 for group 3. The researcher then touches one of the numbers and moves in a predetermined direction, recording the numbers and assigning them to the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients will be assigned to 3 groups. Patients are not relieved of the drug content they receive because the appearance of all medications is the same. Clinical caregivers who give medications to patients also did not know what medication to give. After the course of treatment, to assess the effectiveness of the medication, the assessor does not know which patient has been treated with what medication and only fills in the information related to the questionnaires.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
No. 8, Hezar Jarib Ave., Daneshgh Blvd., Isfahan
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Isfahan
Province
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Postal code
6719674255
Approval date
2020-05-31, 1399/03/11
Ethics committee reference number
IR.MUI.MED.REC.1399.193

Health conditions studied

1

Description of health condition studied
Abdominal Bloating
ICD-10 code
R14.3
ICD-10 code description
Flatulence

Primary outcomes

1

Description
Abdominal Bloadting
Timepoint
Before the start of the study, 2 weeks after the start of the study, 4 weeks after the start of the study, 6 weeks after the start of the study and 8 weeks after the start of the study.
Method of measurement
Questionnaire for bloating and IBS-QOL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Probiotic recipient. Patients on this group receive Familact probiotic tablets from the Zist-takhmir company, containing 7 strains of bacteria (lactobacilli, bifidobacteria, streptococcus thermophilus), will receive every 12 hours after the main meal, and the duration of treatment will be 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group2: Subsalicyte bismuth receptor. Patients in this group will receive 120 mg of bismuth subsalicylate tabletsproduced by Abo-reyhan company every 12 hours after a meal. The duration of treatment will be 8 weeks.
Category
Treatment - Drugs

3

Description
Control group: Plasbo recipient. Patients in this group will use placebo tablets containing starch or a similar appearance to the tablets used in the other two groups for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
Maryam Soheilipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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No. 8, Hezar Jarib Ave., Daneshgh Blvd., Isfahan
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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
Esfahan 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
Maryam Soheilipour
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after people have been identified

When the data will become available and for how long

Late 2020

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Free and on Web Individuals can use the documents by visiting the research sites and the website of Isfahan University of Medical Sciences

From where data/document is obtainable

Free and on Web. Individuals can use the documents by visiting the website of Isfahan University of Medical Sciences and submitting an application

What processes are involved for a request to access data/document

Apply online through the university website and issue a license within about 2 weeks after approval and apply for data access

Comments