Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Investigating the therapeutic effect of Probiotics along with Metronidazole and Probiotics alone in patients with functional flatulence

Protocol summary

Study aim
Determining the therapeutic effect of Probiotics together with Metronidazole and Probiotics alone in patients with functional flatulence

Design
The clinical trial has 2 intervention groups, with parallel groups, double-blind, randomized by table of random numbers. After randomization, patients are divided into 2 groups of 45 people and receive the drugs.

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 2 groups. Patients, 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
Including critera: Age between 20 and 50 years; Having functional abdominal distention according to the Rome III criteria; The first experience of bloating is more than 6 months before the study; Abdominal bloating feeling at least 3 days a month in the last 3 months; Consent to participate in the study Excluding criteria: Any history of chronic inflammatory disease or structural disease of the gastrointestinal tract; Any serious physical problem or disease; Abnormal laboratory data; Severe stress in the last 6 months

Intervention groups
Intervention group 1: At first, for 2 weeks, they will receive 500 mg Metronidazole Tablet of Pars Daru three times a day, and after 2 weeks, they will receive 500 mg FamiLact Probiotic Tablet of Zisttakhmir Company, every 12 hours after the main meals for one month.
Intervention group 2: They will receive 500 mg FamiLact Probiotic Tablet of Zisttakhmir Company, every 12 hours after the main meals for one month.

Main outcome variables
Abdominal bloating

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220916055971N1**
Registration date: **2023-03-22, 1402/01/02**
Registration timing: **prospective**

Last update: **2023-03-22, 1402/01/02**
Update count: **0**

Registration date
2023-03-22, 1402/01/02

Registrant information
Name
Mojtaba Mohammadpour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-05, 1402/02/15
Expected recruitment end date
2023-07-06, 1402/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the therapeutic effect of Probiotics along with Metronidazole and Probiotics alone in patients with functional flatulence

Public title
Metronidazole and Probiotics in functional flatulence patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20 and 50 years Having functional abdominal distention according to the Rome III criteria The first experience of bloating is more than 6 months before the study Abdominal bloating feeling at least 3 days a month in the last 3 months Consent to participate in the study

Exclusion criteria:
Any history of chronic inflammatory disease or structural disease of the gastrointestinal tract Any serious physical problem or disease such as inflammation or malignancy Abnormal laboratory data Use of Calcium Channel Blocker drugs in the last 3 months Severe stress in the last 6 months Positive family history for colon cancer Pregnancy or breastfeeding\

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **45**

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 0-45 for group 1, numbers 46-90 for group 2. 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 2 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.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research, School of Medicine, Isfahan University of Medical Sciences

Street address
Al-Zahra Medical Education Center, Sofe Ave ,Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174675731

Approval date
2022-09-27, 1401/07/05

Ethics committee reference number
IR.MUI.MED.REC.1401.240

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 group 1: At first, for 2 weeks, they will receive 500 mg Metronidazole Tablet of Pars Daru three times a day, and after 2 weeks, they will receive 500 mg FamiLact Probiotic Tablet of Zisttakhmir Company, every 12 hours after the main meals for one month.

Category
Treatment - Drugs

2

Description
Intervention group 2: 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

Recruitment centers

1

Recruitment center

Name of recruitment center
Khorsheid hospital

Full name of responsible person
Maryam Sohilipour

Street address
Korshied hospital, Ostandari Ave, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Gholamreza Askari

Street address
Vice chancellor for research, Isfahan University of Medical Sciences; Faculty of Medicine; Isfahan University of Medical Sciences; Hezar-Jarib Street; Isfahan; Iran

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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
Dr. Maryam Soheilipour

Position
Assistant Professor of Gastroenterology and Hepatology

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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