Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of Probiotics, Metronidazole and Placebo in patients with abdominal flatulence

Protocol summary

Study aim
Determining the therapeutic effect of probiotics, metronidazole and placebo in patients with flatulence

Design
A randomized, triple-blinding clinical trial, with parallel groups, Phase 3 on 80 patients

Settings and conduct
In this triple-blind randomized clinical trial study, 80 patients with functional flatulence referring to the gastroenterology clinic of Al-Zahra Hospital in Isfahan will be included in the study and will be randomly divided into two groups. Metronidazole and probiotics will be prescribed in the intervention group and metronidazole and placebo in the control group. The intervention will be performed in such a way that the patient, the researcher and the statistical analyst will not have any knowledge of the type of intervention. Then, abdominal bloating and quality of life will be evaluated after the intervention.

Participants/Inclusion and exclusion criteria
The inclusion criteria include age between 18 and 70 years, having functional flatulence and consent to participate in the study. Exclusion criteria include having any history of chronic inflammatory disease or structural disease of the gastrointestinal tract, using calcium channel blocking drugs in the last 3 months, having a positive family history for colon cancer, celiac disease, receiving antibiotics or probiotics 8 weeks ago. of study, pregnancy or breastfeeding and alcohol consumption.

Intervention groups
Intervention group: Patients in this group receive metronidazole 500 mg every 8 hours for 2 weeks. Then regflor probiotic containing 200 mg of active lyophilized Bifidobacterium infectis cells is administered once a day 30 minutes before food consumption for 30 days. Control group: Patients in this group receive metronidazole 500 mg every 8 hours for 2 weeks. Then, a placebo pill is prescribed once a day 30 minutes before meals for 30 days.

Main outcome variables
Flatulence; Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230912059417N1**
Registration date: **2024-01-09, 1402/10/19**
Registration timing: **prospective**

Last update: **2024-01-09, 1402/10/19**
Update count: **0**

Registration date
2024-01-09, 1402/10/19

Registrant information

Name
elham tabesh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3620 2020

Email address
tabesh.elham@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of Probiotics, Metronidazole and Placebo in patients with abdominal flatulence

Public title
Investigating the effect of consecutive treatment with antibiotics and probiotics in functional flatulence

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 70 years Having functional flatulence (based on Rome III criteria based on history and risk symptoms and functional flatulence diagnostic criteria) Abdominal flatulence feeling at least 3 days a month in the last 3 months The first experience of flatulence is more than 6 months before the study Informed written 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 Use of calcium channel blocking drugs in the last 3 months Positive family history for colon cancer Celiac disease Any receipt of antibiotics or probiotics 8 weeks before the study Pregnancy or breastfeeding alcohol consumption

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Before starting the study, letter A is written on 40 sheets and letter B is written on 40 sheets, and each is placed in an envelope. Then, each eligible patient who consented to participate in the study is asked to choose an envelope from among the envelopes. In this way, the patient will be randomly assigned to one of the two groups according to the envelope selected without the interference of the researcher.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Probiotic and placebo drugs were numbered by a person unaware of the study, and the participating patients and the specialist doctor who evaluated the patients' flatulence and the assistant who followed up the patients' symptoms were not aware of the type of drug delivered to the patient, which is probiotic or placebo.

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
Sofe Blvd, Al-Zahra Hospital

City
Isfahan

Province
Isfehan

Postal code
8174675731

Approval date
2022-09-05, 1401/06/14

Ethics committee reference number
IR.MUI.MED.REC.1401.213

Health conditions studied

1

Description of health condition studied
Flatulence

ICD-10 code
R14.3

ICD-10 code description
Flatulence

Primary outcomes

1

Description
Bloating severity score

Timepoint
Before of the intervention, 2, 4, 6 and 8 weeks after the start of the study

Method of measurement
Questionnaire IBS- QOL

2

Description
Quality of life

Timepoint

Before of the intervention, 2, 4, 6 and 8 weeks after the start of the study

Method of measurement

Questionnaire IBS- QOL

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group receive metronidazole 500 mg every 8 hours for 2 weeks. Then regflor probiotic containing 200 mg of active lyophilized Bifidobacterium infectis cells is administered once a day 30 minutes before food consumption for 30 days.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group receive metronidazole 500 mg every 8 hours for 2 weeks. Then, a placebo pill is prescribed once a day 30 minutes before meals for 30 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Elham Tabesh

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Sofe Blvd, Al-Zahra Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of Isfahan University of Medical Sciences

Street address

Hezar Jarib Street, Isfahan University of Medical Sciences

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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

Elham Tabesh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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