

# 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

Isfahan

##### 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

###### Street address

Sofe Blvd, Al-Zahra Hospital

###### City

Isfahan

###### Province

Isfahan

###### Postal code

8174675731

###### Phone

+98 31 3620 2020

###### Email

tabesh.elham@med.mui.ac.ir

### 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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Email

tabesh.elham@med.mui.ac.ir

##### 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

###### Street address

Sofe Blvd, Al-Zahra Hospital

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###### Email

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## Person responsible for scientific 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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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Elham Tabesh

**Position**

Assistant Professor

**Latest degree**

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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