

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Synbiotic preparation containing Lactobacillus Spp., Bifidobacter Spp. and Fructo-oligo-saccharide in alleviating constipation symptoms in young men suffering from functional constipation

#### Protocol summary

##### Summary

The objective of this study is to evaluate the effectiveness of Synbiotic preparation containing 108 CFU of Lactobacillus spp., Bifidobacter spp., S.Thermophilus and Prebiotic: Fructooligosaccharide (commercial name: Protexin, London, UK) on constipation symptoms in young men suffering from functional constipation. 66 young men suffering from functional constipation were included (by screening population of young men) in a randomized clinical trial, of whom 60 (Intervention: 31, placebo: 29) completed study period. Functional constipation was defined by Rome 3 criteria. Patients with systemic disorders, fever, recent weight loss, LAP, anemia, Diabetes Mellitus, nervous system disorder, or history of gastrointestinal surgery were excluded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138802151873N1**

Registration date: **2009-06-10, 1388/03/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-06-10, 1388/03/20

##### Registrant information

##### Name

Rouzbeh Fateh

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2242 7617

##### Email address

rouzbehfateh@student.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Aja University of Medical Sciences, research committee

##### Expected recruitment start date

2008-05-10, 1387/02/21

##### Expected recruitment end date

2009-03-11, 1387/12/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Synbiotic preparation containing Lactobacillus Spp., Bifidobacter Spp. and Fructo-oligo-saccharide in alleviating constipation symptoms in young men suffering from functional constipation

##### Public title

Synbiotic preparation in young men suffering from functional constipation, a randomized clinical trial.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Male sex, age 18-40 years, Fulfill Rome III criteria, giving informed consent Exclusion criteria: Presence of alarming symptoms like fever, recent weight loss, LAP, anemia, presence of any systemic disorder like Diabetes Mellitus or nervous system disorder like M.S., history of gastrointestinal surgery

##### Age

From **18 years** old to **40 years** old  
**Gender**  
Male  
**Phase**  
N/A  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **66**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**  
Randomization was done with block method.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Aja University of Medical Sciences ethics committee

##### Street address

Aja University of Medical Sciences, Fatemi ave.

##### City

Tehran

##### Postal code

14185/611

#### Approval date

2008-05-01, 1387/02/12

#### Ethics committee reference number

20/ 1 / 9158 / ج/الف 1

## Health conditions studied

### 1

#### Description of health condition studied

functional constipation

#### ICD-10 code

K59.0

#### ICD-10 code description

other functional intestinal disorders-constipation

## Primary outcomes

### 1

#### Description

Stool form and consistency

#### Timepoint

Baseline, weeks 2 and 4

#### Method of measurement

Bristol stool form scale

### 2

#### Description

Bowel movement frequency per week

#### Timepoint

Baseline, weeks 2 and 4

#### Method of measurement

Designed questionnaire

### 3

#### Description

Severity of constipation symptoms

#### Timepoint

Baseline, weeks 2 and 4

#### Method of measurement

PAS-sym questionnaire

## Secondary outcomes

### 1

#### Description

Effectiveness of treatment

#### Timepoint

Baseline and week 4

#### Method of measurement

Designed questionnaire

### 2

#### Description

Need to use manual manoeuvres

#### Timepoint

Baseline and week 4

#### Method of measurement

Designed questionnaire

### 3

#### Description

Use of laxatives

#### Timepoint

Baseline and week 4

#### Method of measurement

Designed questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Synbiotic capsule, containing 108 CFU of Lactobacillus spp., Bifidobacter spp., S.Thermophilus and Prebiotic: Fructooligosaccharide (commercial name: Protexin, London, UK), twice a day (after breakfast and after dinner) for 4 weeks

**Category**

Treatment - Drugs

**2****Description**

Control group: placebo capsule with the same shape and color, twice a day (after breakfast and after dinner) for 4 weeks

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

501 hospital and AJA University of Medical Sciences

**Full name of responsible person**

Ms. Roshandel

**Street address**

501 hospital, Fatemi Ave.

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Aja University of Medical Sciences

**Full name of responsible person**

Dr. Dorrmanesh

**Street address**

Aja University of Medical Sciences, Fatemi ave.

**City**

Tehran

**Grant name**

230 / 111200

**Grant code / Reference number**

10514300

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Aja University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Rouzbeh Fateh

**Position**

M.D.

**Other areas of specialty/work****Street address**

no.18, Keyhan st., Moghaddas Ardebili Ave., Zafaranieh

**City**

Tehran

**Postal code**

19868-73613

**Phone**

+98 21 2242 7617

**Fax**

+98 21 2242 7980

**Email**

rouzbehfateh@student.tums.ac.ir /

rouzfa@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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rouzfa@yahoo.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*