

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

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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**

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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