Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

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

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)

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+98 21 2242 7617

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Recruitment status

Recruitment complete

Funding source

Aja Universiy 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 constiption

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 / 1الف/ ج

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 maneuvres

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
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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