

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluating The Effects of Lactobacillus Sporogenes in Combination with Mineral Oil Compared with Mineral Oil Alone on Symptoms of Constipation in Children aged 2 to 15 Years with Functional Constipation

Protocol summary

Summary

We aimed to evaluate the effects of a Probiotic containing Lactobacillus Sporogenes in combination with mineral oil compared with mineral oil alone on symptoms of constipation in children. This controlled trial was conducted in 2010-2011 in Isfahan on 60 children (aged 2 to 15 years) with functional constipation (based on the Rome III criteria) referred to a pediatric gastroenterology clinic. Those with immunocompromised conditions and those receiving antibiotics were not included. Children randomly (based on random table numbers) received the Probiotic (Lactol®, composed of Lactobacillus Sporogenes, 1 Tab/20kg/d) plus mineral oil (Paraffin 1 ml/kg/d) or the mineral oil alone (Paraffin 1 ml/kg/d) for two months. Symptoms of constipation were the primary measures including defecation frequency, stool form, strain and pain at defecation, incomplete evacuation and soiling which were assessed by the Rome III questionnaire and compared before and 2 months after the intervention. After the treatment period, the two groups were also compared with regards to global improvement as the secondary measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207311579N1**
Registration date: **2012-09-11, 1391/06/21**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-09-11, 1391/06/21

Registrant information

Name

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Name of organization / entity

Medical Students' Research Center, Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Islamic Azad University, Najafabad Branch

Expected recruitment start date

2010-01-05, 1388/10/15

Expected recruitment end date

2011-02-04, 1389/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating The Effects of Lactobacillus Sporogenes in Combination with Mineral Oil Compared with Mineral Oil Alone on Symptoms of Constipation in Children aged 2 to 15 Years with Functional Constipation

Public title

Efficacy of Probiotic in the Treatment of Childhood Functional Constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Children 2 to 15 years of age, 2- Having functional constipation based on the Rome III criteria, 3- Parents' Consent for Participation. Exclusion Criteria: 1- Those with immunocompromised condition or other severe diseases, 2- Those receiving antibiotic in the previous four weeks, 3- Experiencing severe side effects, gastroenteritis, or receiving antibiotic for any reason during the study period.

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Islamic Azad University,
Najafabad Branch

Street address

University Ave.

City

Najafabad

Postal code

Approval date

2010-01-05, 1388/10/15

Ethics committee reference number

150101018772055

Health conditions studied

1

Description of health condition studied

Childhood Functional Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Symptoms of constipation

Timepoint

Before and 2 months after treatment

Method of measurement

Rome III questionnaire

Secondary outcomes

1

Description

Global improvement

Timepoint

Two months after treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Controls: Mineral oil (Paraffin 1 ml/kg/d) for 8 weeks

Category

Treatment - Drugs

2

Description

All children: Toilet training and dietary advices

Category

Behavior

3

Description

Intervention: Synbiotic (Lactol®, Bioplus Life Sciences Pvt. 1 Tab/20kg/d) plus mineral oil (Paraffin 1 ml/kg/d) for 8 weeks. The synbiotic used in this study composed of the followings; Lactobacillus Sporogenes (15 × 10⁷ Spores), Fructo-Oligosaccharides, Microcrystalline Cellulose, Sodium starch Glycolate, Povidone, Hypermellose Stearate, Silicon Dioxide, and Propylene Glycol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra University Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Islamic Azad University,
Najafabad Branch
Full name of responsible person
Dr. Reza Ebrahimi
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University Ave.
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Grant name

بررسی اثر سین بیوتیک در درمان بیوست فانکشنال کودکان مراجعه
کننده به بیمارستان الزهرا (س) اصفهان سال 1388-1389

Grant code / Reference number

15010101872055

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

Yes

Title of funding source

Vice chancellor for research, Islamic Azad University,
Najafabad Branch

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
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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