Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

The Role of Synbiotic in the Treatment of Childhood Constipation

Protocol summary

Summary

Constipation is a common problem in children. There is some clinical evidence for the role of probiotics in the treatment of constipated children. This study is about the therapeutic effect of synbiotic (combination of probiotic and prebiotic) in treatment of childhood constipation. In a double-blind randomized placebo controlled study (RCTs) 102 children, aged 4–12 years, with functional constipation according to Rome III criteria were assessed for 4 weeks. They were randomized in 3 groups: Group A received 1.5 ml/kg/day oral liquid paraffin plus placebo, group B received 1 sachet of synbiotic per day plus placebo and group C received 1.5 ml/kg/day oral liquid paraffin plus 1 sachet of synbiotic per day. Frequency of bowel movements (BMs), stool consistency, number of fecal incontinence episodes, abdominal pain, painful defecation per week, success treatment, and side effects determined in each group before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811193309N1**
Registration date: **2010-04-20, 1389/01/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-04-20, 1389/01/31

Registrant information

Name

Mozhgan Sabbaghian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-01, 1388/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Role of Synbiotic in the Treatment of Childhood Constipation

Public title

The Role of Synbiotic in the Treatment of Childhood Constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 4-12 years, diagnosis based on Room III criteria as two months of at least 2 or more of the following: less than 2 defecation in the toilet per week, more than 1 episode of fecal incontinence per week, history of retentive posturing or excessive volitional stool retention, history of painful or hard bowel movements, presence of a large fecal mass in the rectum, history of large diameter stools that may obstruct the toilet. Exclusion criteria: presence of organic causes for constipation; including Hirschsprung’s disease, spina bifida occulta, hypothyroidism, cystic fibrosis, neurologic abnormalities and intestinal pseudo-

obstruction

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Deputy of Tehran University of Medical Sciences

Street address
Tehran University of Medical Science, 16 Azar St.

City
Tehran

Postal code

Approval date
2010-02-08, 1388/11/19

Ethics committee reference number
88/ S /130/1771

Health conditions studied

1

Description of health condition studied
Other diseases of intestines

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
Frequency of bowel movements per week

Timepoint
4 weeks

Method of measurement
Questionnarie

2

Description
Stool consistency

Timepoint
4 Weeks

Method of measurement
Questionnarie

3

Description
Frequency of stool incontinence per week

Timepoint
4 Weeks

Method of measurement
questionnarie

4

Description
Abdominal pain

Timepoint
4 weeks

Method of measurement
questionnarie

5

Description
Painful defecation

Timepoint
4 weeks

Method of measurement
Questionnarie

Secondary outcomes

1

Description
Success treatment

Timepoint
4 weeks

Method of measurement
Success treatment defined as ≥ 3 Bowel Movements per week,≤ 2 incontinence per month and no abdominal pain

2

Description
Adverse effects

Timepoint
4 weeks

Method of measurement
Questionnarie

Intervention groups

1

Description
1.5 ml/kg/day oral liquid paraffin plus placebo (placebo sachet with the same shape and color to synbiotic)
Category
Treatment - Drugs

2

Description
1 sachet of synbiotic per day (Restore 1 billion CFU/1 sachet, Made by Protexin Co. in UK, synbiotic combination were probiotic strains containing L. casei, L. rhamnosus, S. thermophilus, B. breve, L. acidophilus, B. infantis and Fructooligosaccharide as prebiotic) and placebo (with the same shape and color to paraffin oil)
Category
Treatment - Drugs

3

Description
1.5 ml/kg/day oral liquid paraffin and 1 sachet of synbiotic per day (Restore 1 billion CFU/1 sachet, Made by Protexin Co. in UK, synbiotic combination were probiotic strains containing L. casei, L. rhamnosus, S. thermophilus, B. breve, L. acidophilus, B. infantis and Fructooligosaccharide as prebiotic)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children Medical Center Hospital
Full name of responsible person
Mozhgan Sabbaghian
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mozhgan Sabbaghin
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Department of Gastroenterology, Children Medical Center Hospital, Tehran University of Medical Science
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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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