

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The comparison of the efficacy of a synbiotic containing “Bifidobacterium infantis”, “Lactobacillus reuteri” and “Lactobacillus rhamnosus”(Pedilact drop) with a synbiotic containing “Bifidobacterium lactis”(BB care drop) in the treatment of infantile functional constipation

Protocol summary

Study aim

A therapeutic goal including : "Comparing the efficacy of Pedilact drop with BBcare drop in the treatment of infantile functional constipation".

Design

A randomized double blind clinical trial

Settings and conduct

80 infants will be randomly assigned into two groups of 40 infants. Group A will receive nonpharmacological treatment + Pedilact drop ; 5 drops QID. Group B will receive nonpharmacological treatment + BBcare drop ; 5 drops QID for 30 days. The data will be recorded in separate questionnaires for each infant and then will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infants under 1 year of age who have at least 2 characteristics of the following criteria for 1 month : 1. Two or fewer defecations per week 2. History of excessive stool retention 3. History of painful or hard bowel movements 4. History of large-diameter stools 5. Presence of a large fecal mass in the rectum. Exclusion criteria : GI Obstruction or surgery ; Receiving opiates, muscle relaxants and sedatives ; Mechanical ventilation; Underlying diseases, Central and Peripheral nervous system abnormalities, ; Irritable bowel syndrome ; Endocrine Diseases(Hypothyroidism) ; anorectal abnormalities; receiving probiotics products since one week before intervention.

Intervention groups

Group A intervention: They will receive nonpharmacological treatment + a synbiotic containing “Bifidobacterium infantis”, “Lactobacillus reuteri” and “Lactobacillus rhamnosus”(Pedilact drop) Group B intervention: They will receive nonpharmacological treatment + a synbiotic containing “Bifidobacterium Lactis”(BBcare drop)

Main outcome variables

Response rate of clinical manifestations of infantile constipation to each synbiotic in each group

General information

Reason for update

Acronym

درمان بیوست شیرخواران

IRCT registration information

IRCT registration number: **IRCT20160827029535N7**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-22, 1398/12/03**

Update count: **0**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

Peymaneh Alizadeh Taheri

Name of organization / entity

Tehran University of Medical Sciences, Bahrami Hospital

Country

Iran (Islamic Republic of)

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+98 21 7301 3420

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alizadep@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-09, 1398/11/20
Expected recruitment end date
2020-07-20, 1399/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The comparison of the efficacy of a synbiotic containing "Bifidobacterium infantis", "Lactobacillus reuteri" and "Lactobacillus rhamnosus"(Pedilact drop) with a synbiotic containing "Bifidobacterium lactis"(BB care drop) in the treatment of infantile functional constipation

Public title

The comparison of the efficacy of two different synbiotics in the treatment of infantile functional constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Must include 1 month of at least 2 of the following in infants up to 4 years of age:1.Two or fewer defecations per week 2.History of excessive stool retention 3. History of painful or hard bowel movements 4. History of large-diameter stools 5. Presence of a large fecal mass in the rectum

Exclusion criteria:

GI Obstruction or previous GI surgery ; Receiving opiates, muscle relaxants and sedatives ; Mechanical ventilation; Underlying diseases, Central and Peripheral nervous system diseases ; Irritable bowel syndrome ;Endocrine Diseases(Hypothyroidism) ; anorectal abnormalities; receiving probiotics products since one week before intervention

Age

To 1 year old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization at the individual level and using random number table with allocation concealment by sequentially numbered sealed opaque envelop

Blinding (investigator's opinion)

Double blinded

Blinding description

The caregivers who administers the drug, the

researcher who completes the questionnaires and collected the data, and the statistician who analyzed the data are blinded throughout the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran university Of Medical Sciences, Pursina Street, Ghods Avenue, Enghelab Square

City

Tehran

Province

Tehran

Postal code

1416753955

Approval date

2019-12-10, 1398/09/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.644

Health conditions studied

1

Description of health condition studied

Infantile functional constipation

ICD-10 code

k59.0

ICD-10 code description

Other diseases of intestines

Primary outcomes

1

Description

Response rate of clinical manifestations of infantile constipation to each synbiotic in each group

Timepoint

One week and one month after beginning of intervention

Method of measurement

Questionnaire according to the new Rome IV criteria

Secondary outcomes

1

Description

Complications of each drug (diarrhea, vomiting and skin rash) during intervention

Timepoint

One week and one month after intervention

Method of measurement

Questionnaire according to the occurrence of diarrhea, vomiting and skin rash

Intervention groups

1

Description

Group A intervention: They will receive nonpharmacological treatment +a synbiotic containing "Bifidobacterium infantis", "Lactobacillus reuteri" and "Lactobacillus rhamnosus"(Pedilact drop)

Category

Treatment - Drugs

2

Description

Group B intervention: They will receive nonpharmacological treatment +a synbiotic containing "Bifidobacterium Lactis "(BB care drop)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami Hospital

Full name of responsible person

Peymaneh Alizadeh Taheri

Street address

Bahrami Hospital, Shahid Kiaii Street,Damavand Avenue, Imam Hosein Square

City

Tehran

Province

Tehran

Postal code

1641744991

Phone

+98 21 7301 3420

Email

p.alizadet@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Peymaneh Alizadeh Taheri

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Peymaneh Alizadeh Taheri

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available