Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 seperate questioners for each infant and then will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infants under1 year of age who have at least 2 characteristics of the following chriteria 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 Obstraction or surgery ; Recieving opiates, muscle relaxants and sedatives ; Mechanical ventilation; Underlying diseases, Central and Pripheral nervous system abnormalities, ; Irritable bowel syndrome ;Endocrine Diseases(Hypothyroidism) ; anorectal abnormalities; recieving probiotics products since one week before intervention.

Intervention groups

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

Phone

+98 21 7301 3420

Email address

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 Obstraction or previous GI surgery ; Recieving opiates, muscle relaxants and sedatives ; Mechanical ventilation; Underlying diseases, Central and Pripheral nervous system diseases ; Irritable bowel syndrome ;Endocrine Diseases(Hypothyroidism) ; anorectal abnormalities; recieving 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 administeres 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

Infantie 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 rush) during intervention
Timepoint
One week and one month after intervention
Method of measurement
Questionnaire according to the occurance of diarrhea, vomiting and skin rush

Intervention groups

1

Description
Group A intervention: They will recieve nonpharmacological treatment +a synbiotic containing “Bifidobacterium infantis”, “Lactobacillus reuteri” and “Lactobacillus rhamnosus”(Pedilact drop)
Category
Treatment - Drugs

2

Description
Group B intervention: They will recieve 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
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1641744991
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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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Bahrami Hospital, Shahid Kiaii Street,Damavand Avenue, Imam Hosein Square
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Email
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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
Street address
Bahrami Hospital, Shahid Kiaii Street,Damavand Avenue, Imam Hosein Square
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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