

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The comparison of the efficacy of a synbiotic containing “Bifidobacterium infantis”, “Lactobacillus reuteri” and “Lactobacillus rhamnosus” with a synbiotic containing “Bifidobacterium lactis” in the treatment of infantile colic

Protocol summary

Study aim

Comparing the efficacy of two synbiotics in the treatment of infantile colic

Design

A randomized double blind clinical trial with simple randomization at the individual level and using table of random numbers; allocation concealment by sequentially numbered sealed opaque envelop. Infants in group A will receive Pedilact (containing “Bifidobacterium infantis”, “Lactobacillus reuteri” and “Lactobacillus rhamnosus”) and Infants in group B will receive BB care (containing “Bifidobacterium lactis”). Both groups will receive 5 drops of each drug every 6 hours for one month.

Settings and conduct

The neonates with clinical GERD will be randomly assigned into two groups each containing 35 ones in Bahrami hospital. Infants in group A will receive Pedilact (containing “Bifidobacterium infantis”, “Lactobacillus reuteri” and “Lactobacillus rhamnosus”) and Infants in group B will receive BB care (containing “Bifidobacterium lactis”). Both groups will receive 5 drops of each drug every 6 hours. The participants; physicians, nurses and mothers who care the participants; the researcher who collect the data and the person who analyses the data are blind to the study. Zist-Takhmir company has produces both synbiotics as BB care drop with two different red and yellow lables. Nobody knows about the content of the bottles except the main researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Breast feeding infants of 3 weeks to 3 months of age fulfilling the Wessel’s criteria including: crying for at least 3 hours per day, for at least 3 days per week, and for at least 3 weeks from birth to 3-4 months of age or having characteristic clinical manifestations of colic including irritability, crying ,flushing and passage of a large amount of bowel gas along with defecation;

irritability and crying especially in the evening and increased bowel sounds in auscultation 3-No apparent cause or failure to thrive ; Exclusion criteria: 1-Having any diseases, especially GI tract ones 2-Receiving any other drugs at the time of the study except multivitamins.

Intervention groups

In group A Pedilact (containing “Bifidobacterium infantis”, “Lactobacillus reuteri” and “Lactobacillus rhamnosus”) will be administered as 5 drops QID and In group B BB care (containing “Bifidobacterium lactis”) will be administered as 5 drops QID for one month..

Main outcome variables

1-The rate of clinical response to each symbiotic. 2-The occurrence rate of side effects of each symbiotic.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160827029535N4**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **prospective**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

Registration date

2018-02-07, 1396/11/18

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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Recruitment status

Recruitment complete

Funding source

Invstigator

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2019-04-19, 1398/01/30

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" with a synbiotic containing "Bifidobacterium lactis" in the treatment of infantile colic

Public title

The Comparison of two synbiotics in the treatment of infantile colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1-Breast-fed infants with the age of 3 weeks to 3 months
2- Fulfilling the Wessel's criteria including: crying for at least 3 hours per day, for at least 3 days per week, and for at least 3 weeks from birth to 3-4 months of age or the characteristic clinical manifestations of colic including irritability, crying ,flushing and passage of a large amount of bowel gas along with defecation; irritability and crying especially in the evening and increased bowel sounds in auscultation
3-No failure to thrive .

Exclusion criteria:

1-any acute or chronic diseases, especially GI tract conditions
2- use of medications except routine supplements

Age

From **21 days** old to **4 months** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization at the individual level and using table of random numbers; allocation concealment by sequentially numbered sealed opaque envelop

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants; physicians, nurses and mothers who care the participants; the researcher who collect the data and the person who analyses the data are blind to the study. Zist-Takhmir company has produces both synbiotics as BB care drop with two different red and yellow lables .Nobody knows about the content of the bottles except the main researcher.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

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

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-08-06, 1396/05/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.3058

Health conditions studied

1

Description of health condition studied

Infantile colic

ICD-10 code

R 10.4

ICD-10 code description

Abdominal pain

Primary outcomes

1

Description

Response rate of infantile colic symptoms and signs

Timepoint

Before intervention, one week and one month after beginning of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Complications of each synbiotic during intervention including vomiting, constipation, skin reactions and infections.

Timepoint

Before intervention, one week and one month after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Group A intervention: Administering a synbiotic containing "Bifidobacterium infantis", "Lactobacillus reuteri" and "Lactobacillus rhamnosus". Zist-Takhmir company has produces this drop as BB care drop with red lable for the present search study. It is administered 5 drop every 6 hours for one month.

Category

Treatment - Drugs

2

Description

Intervention group: Group B intervention: Administering a synbiotic containing "Bifidobacterium lactis". Zist-Takhmir company has produces this drop as BB care drop with yellow label for the present search study. It is administered 5 drop every 6 hours for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami hospital

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

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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

Investigator

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences. Bahrami Hospital

Full name of responsible person

Peymaneh Alizadeh Taheri

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Position

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Latest degree

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Other areas of specialty/work

Pediatric, Neonatology

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Position

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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