

# 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)

**Phone**

+98 21 7301 3420

**Email address**

alizadep@tums.ac.ir

**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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1641744991

##### Phone

+98 21 2278 2896

##### Fax

+98 21 7756 8809

##### Email

p.alizadet@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Investigator

##### Full name of responsible person

Peymaneh Alizadeh Taheri

##### Street address

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

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

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Peymaneh Alizadeh Taheri

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric, Neonatology

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**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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**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