Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim

A therapeutic goal including :"Comparing the efficacy of a synbiotic drop with dimeticone drop in the treatment of infantile colic".

Design

Design: A randomized tripple blind clinical trial

Settings and conduct

Participants: 70 infants with inclusion criteria of the new Rome IV for diagnosis of infantile colic, refering to Bahrami Hospital. Setting and conduct:The infants will be randomly assigned into two groups. Each group containes 35 infants. Intervention: Infants in group A will receive nonpharmacological treatment + Pedilact drop(containing “Bifidobacterium infantis”, “Lactobacillus reuteri” and “Lactobacillus rhamnosus”); 5 drops every 6 hours and Infants in group B will receive nonpharmacological treatment + dimeticone drop ; 7-10 drops every 6 hours. Length of Intervention:The rate of clinical manifestations and side effects of each drug will be recordedon the 7th and 30th day after intervention.The data will be recorded in seperate questioners for each infant and then will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Breast-fed infants under 5 months of age fulfilling the new Rome IV criteria for diagnosis of infantile colic. Exclusion criteria: 1-any acute or chronic diseases, especially GI tract problems 2- Recieving antibiotics or supplements containing probiotics or prebiotics 1 week prior to the study 3- Parents' unwilling to participate in the study4-Protein milk allergic cases

Intervention groups

1-Group A intervention: They will recieve nonpharmacological treatment + a synbiotic containing “Bifidobacterium infantis”, “Lactobacillus reuteri” and “Lactobacillus rhamnosus”. 2-Group B intervention: They will recieve nonpharmacological treatment + "dimeticone drop”

Main outcome variables

Recovery rate of clinical manifestations of infantile colic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160827029535N6**
Registration date: **2019-09-13, 1398/06/22**
Registration timing: **prospective**

Last update: **2019-09-13, 1398/06/22**
Update count: **0**

Registration date

2019-09-13, 1398/06/22

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

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 dimeticone drop in the treatment of infantile colic

Public title

The comparison of the efficacy of a synbiotic drop with dimeticone drop in the treatment of infantile colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Any healthy infant Under 5 months of age Diagnosed as colic according to the new Rome IV criteria

Exclusion criteria:

Any acute or chronic diseases, especially GI tract conditions Taking antibiotics or supplements of probiotics or prebiotics since 1 week prior to the study Not fulfilling the new Rome IV criteria Parents' unwilling to participate in the study. Protein milk allergy

Age

To **5 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **35**

Any healthy infant under 5 months of age with the diagnosis of colic according to the new Rome IV criteria who has not received antibiotics or supplements of probiotics or prebiotics since1 week prior to the study

Randomization (investigator's opinion)

N/A

Randomization description

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

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

2019-05-31, 1398/03/10

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.139

Health conditions studied

1

Description of health condition studied

Infantile colic

ICD-10 code

K52.3

ICD-10 code description

Indeterminate colitis

Primary outcomes

1

Description

Recovery rate of infantile colic symptoms and signs

Timepoint

One week and one month after beginning of intervention

Method of measurement

Questionnaire

2

Description

Complications of each drug during intervention

Timepoint

One week and one month after beginning of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Recovery rate of infantile colic symptoms and signs

Timepoint
One week one month after beginning of intervention
Method of measurement
Questionnaire

2

Description
Complications of each drug (diarrhea, vomiting and skin rush) during intervention
Timepoint
One week and one month after intervention
Method of measurement
Questionnaire

Intervention groups

1

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

2

Description
Group A intervention: They will recieve nonpharmacological treatment +Dimeticon 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,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Tehran
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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
Persons

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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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