

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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 contains 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 recorded on the 7th and 30th day after intervention. The data will be recorded in separate 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- Receiving antibiotics or supplements containing probiotics or prebiotics 1 week prior to the study 3- Parents' unwilling to participate in the study 4-Protein milk allergic cases

Intervention groups

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

alizadep@tums.ac.ir

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 since 1 week prior to the study

Randomization (investigator's opinion)

N/A

Randomization description

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

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 rash) during intervention

Timepoint

One week and one month after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Group A intervention: They will receive nonpharmacological treatment +a synbiotic containing "Bifidobacterium infantis", "Lactobacillus reuteri" and "Lactobacillus rhamnosus" Intervention group:

Category

Treatment - Drugs

2

Description

Group A intervention: They will receive 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,

City

Tehran

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1641744991

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

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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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
Subspecialist
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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