

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Compare the effect of probiotics "(Bifidobacterium Infantis, Lactobacillus Reuteri, Lactobacillus Rhamnosus)" and placebo in the treatment of infantile colic

Protocol summary

Summary

Infantile colic is a benign and common disorder. The disease occurs in the first 3-4 months of age. The disease presents with strong crying and irritability. This study was a randomized double-blind placebo-controlled trial. In the study, 70 Infants aged 21 days to 4 months with Wessel criteria that referred to Bahrami Children's Hospital in Tehran, were enrolled. The main inclusion criteria include: the infants with crying at least 3 hours a day; for at least 3 days a week; The main exclusion criteria include: the children with organic gastrointestinal disorders; consumption of any antibiotic, probiotics and formula containing probiotics and other medications for colic before entering the study; The infants were randomly divided in two groups (case and control groups). The first group (case group) was given probiotic from Bifidobacterium Infantis, Lactobacillus Reuteri, and Lactobacillus Rhamnosus strain (Pedilact® brand manufactured by Iranian company, Zist Takhmir) with dose 5 drops per day orally for 4 weeks. The second group (control group) received placebo for the same period. Patients were followed up on days 7, 21 and 30 after initiation of treatment. In the follow up period these items were recorded: duration of crying, number of crying attacks per day, crying day in week and drug side effects. The purpose of the study was to evaluate the effect of probiotics in treatment of infantile colic.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120818971N4**
Registration date: **2016-12-27, 1395/10/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-27, 1395/10/07

Registrant information

Name

Kambiz Eftekhari

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 7301 3000

Email address

k-eftekhari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Tehran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of probiotics "(Bifidobacterium Infantis, Lactobacillus Reuteri, Lactobacillus Rhamnosus)" and placebo in the treatment of infantile colic

Public title

The effect of probiotics in the treatment of infantile colic

Purpose

Treatment

Inclusion/Exclusion criteria

The main inclusion criteria include: the infants with crying at least 3 hours a day; for at least 3 days a week; The main exclusion criteria include: the children with organic gastrointestinal disorders; consumption of any antibiotic, probiotics and formula containing probiotics and other medications for colic before entering the study;

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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

City

Tehran

Postal code

Approval date

2016-11-13, 1395/08/23

Ethics committee reference number

IR-TUMS-MEDICINE.REC.1395.1015

Health conditions studied

1

Description of health condition studied

Infantile colic

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal pain

Primary outcomes

1

Description

Duration of crying

Timepoint

on days 7, 21 and 30 after initiation of treatment

Method of measurement

Questionnaire

2

Description

Crying day in week

Timepoint

on days 7, 21 and 30 after initiation of treatment

Method of measurement

Questionnaire

3

Description

Number of crying and irritability attacks per day

Timepoint

on days 7, 21 and 30 after initiation of treatment

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Vomiting

Timepoint

On days 7, 21 and 30 after initiation of treatment

Method of measurement

Questionnaire

2

Description

Constipation

Timepoint

On days 7, 21 and 30 after initiation of treatment

Method of measurement

Questionnaire

3

Description

Skin reactions

Timepoint

On days 7, 21 and 30 after initiation of treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

The first group (interventional group) was given Pedilact with dose 5 drops per day orally for 4 weeks.

Category

Treatment - Drugs

2

Description

The second group (control group) received placebo with dose 5 drops per day orally for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami Children's Hospital

Full name of responsible person

Kambiz Eftekhari

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhondzadeh

Street address

Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Kambiz Eftekhari

Position

Assistant professor of pediatric Gastroenterology

Other areas of specialty/work

Street address

Bahrami Children's Hospital

City

Tehran

Postal code

Phone

+98 21 7301 3210

Fax

Email

k-eftekhari@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Kambiz Eftekhari

Position

Assistant professor of Pediatric Gastroenterology

Other areas of specialty/work

Street address

Bahrami Children's Hospital

City

Tehran

Postal code

Phone

+98 21 7301 3210

Fax

Email

k-eftekhari@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Kambiz Eftekhari

Position

Assistant professor of Pediatric Gastroenterology

Other areas of specialty/work

Street address

Bahrami Children's Hospital

City

Tehran

Postal code

Phone

+98 21 7301 3210

Fax

Email

k-eftekhari@sina.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty