

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of probiotic in reducing infant colic compared to placebo

Protocol summary

Study aim

Investigating the effect of probiotic on reducing the infantile colic

Design

This study was performed on 120 colic coliforms referred to the pediatric medical center of Tehran, randomly divided into two equal groups using randomized blocks.

The first group(A), which contains 60 infants, is given 5 drops of drop pedilact for 4 weeks (product of the zist takhmir company). The second group(B) is given 5 drops of placebo for 4 weeks (product of the zist takhmir company) . The method of selecting subjects in two groups (A and B) is completely randomized, based on blocks randomization. Demographic data including age, sex, maternal age, side effects, crying time duration, fecal consistency, before and every week after the start of the drug or placebo and the parents' satisfaction is recorded.

Settings and conduct

The place of study is the gastroenterology Clinic of the Children's Medical Center.

Participants/Inclusion and exclusion criteria

In this study, 120 full term infantile colic with birth weight greater than 2500 gram and 21 to 90 days of age who are breast fed without any underlying problem or disease, are included in the study. When taking antibiotics and probiotics by infant, or taking probiotics by mother, or getting acute and febrile illness, and ... are excluded.

Intervention groups

In this study, each of the infants in group A receive 5 drops of Pedi lact(manufactured by Zist- takhmir company) before feeding once a day for 4 weeks. and each of infants in group B receive 5 drops of Placebo (manufactured by Zist- takhmir company) before feeding once a day for 4 weeks.

Main outcome variables

time of crying

General information

Reason for update

Acronym

The effect of probiotic on infantile colic

IRCT registration information

IRCT registration number: **IRCT20151129025287N3**

Registration date: **2018-01-08, 1396/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-08, 1396/10/18**

Update count: **0**

Registration date

2018-01-08, 1396/10/18

Registrant information

Name

Shokufe Ahmadipour

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3341 1439

Email address

ahmadipour.sh@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

tehran university of medical science

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic in reducing infant colic compared to placebo

Public title

The effect of probiotic in reducing infant colic compared to placebo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of the infant 21 to 90 days full term birth weight > 2500 grams breastfeed Parental satisfaction to enter the study

Exclusion criteria:

any illness or digestive disorders attending other clinical trials acute illness, fever, diarrhea Use of antibiotics or another probiotics by the infant Probiotic use by the mother formula feed

Age

From **21 days** old to **3 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

infants are randomized (using randomized 2 blocks) to be divided into equal groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, both infants' parents and doctors prescribing (drug or placebo drops) are completely unaware, but parents are told that they may randomly give the placebo drop to him/her infant

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

Gharib Ave., End of Keshavarz Blv

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

IR.TUMS.CHMC.REC.1396.3796

Health conditions studied**1****Description of health condition studied**

Other and unspecified abdominal pain

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal pain

Primary outcomes**1****Description**

crying hours

Timepoint

weekly

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

stool Consistency

Timepoint

weekly

Method of measurement

Questionnaire

Intervention groups**1****Description**

In the intervention group, 5 drops of pediatric drops (made by zist- takhmir company) is given daily for 4 weeks.

Category

Treatment - Drugs

2**Description**

Control group: 5 drops of placebo drops (made by the zist- takhmir company) is given daily for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Shokoufeh Ahmadipour

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Children's Medical Center., Gharib Ave., End of Keshavarz Blv

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1419733151

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ahmadipour_sh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

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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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shokoufeh Ahmadipour

Position

Fellow of Pediatric's Gastroenterology

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Gholam hosein Fallahi

Position

Professor, Pediatric's Gastroenterologist

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shokoufeh Ahmadipour

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Fax**Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Some of the data, such as information on the main outcome, can be shared.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academia and scientific departments

Under which criteria data/document could be used

Understanding Data Analysis Method

From where data/document is obtainable

E-mail

What processes are involved for a request to access data/document

Through email with correspondence and providing a code of ethics certificate from his/her university

Comments