

# 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733151

**Phone**

+98 21 6147 2014

**Email**

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**

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

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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**

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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ahmadipour\_sh@yahoo.co

**Web page address**

**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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dr.ghfallahi@yahoo.com

**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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**Province**

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**Postal code**

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**Phone**

+98 21 6147 2014

**Fax****Email**

ahmadipour\_sh@yahoo.com

**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**