

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of probiotic in treatment of infantile colic in children

#### Protocol summary

##### Summary

This clinical trial was carried out to assess the effects of probiotics in the treatment of infantile colic in 84 breast fed and formula fed infants that have age less than 13 weeks who referred to Arak AmirKabir hospital Based on inclusion criteria: infantile colic (crying and restlessness more than 3 hours a day for more than 3 days a week); age less than 3 months, more than 36 weeks gestational age at birth, birth weight greater than 2500 g and Exclusion criteria: growth retardation, medical problems( immune compromise, genetic disorders) or taking solids, antibiotics or kidilact. Children were Randomly assigned in two groups, case groups: (treated with 5 drops once daily dose of probiotic Pedilact and voice and vocal technique recommended to reduce colic include: rhythmic rocking motion, walking, mild tremor, etc.) and the control group (only recommend techniques for reducing colic), respectively. Clinical improvement of infants was assessed within 28 days after start of intervention. Outcome variables were crying attacks, restlessness, and crying time in infants within 24 hours.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016111023876N3**

Registration date: **2017-03-11, 1395/12/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-03-11, 1395/12/21

##### Registrant information

###### Name

Fatemeh Dorreh

###### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86334172517

##### Email address

doreh.f@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2015-06-24, 1394/04/03

##### Expected recruitment end date

2015-12-24, 1394/10/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of probiotic in treatment of infantile colic in children

##### Public title

The effect of probiotic in treatment of infantile colic

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: infantile colic (crying and restlessness more than 3 hours a day for more than 3 days per week); age < 3 months, more than 36 weeks gestational age at birth, birth weight greater than 2500 g Exclusion criteria: growth retardation , medical problems (immune compromise genetic disorders or significant growth retardation), taking solids, antibiotics or kidilact

##### Age

To **3 months** old

##### Gender

Both

## Phase

1

### Groups that have been masked

No information

### Sample size

Target sample size: 84

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics Committee of the Arak University of Medical Sciences

#### Street address

Arak, Street Rahe Ahan, Alley Maskan

#### City

Arak

#### Postal code

### Approval date

2013-05-22, 1392/03/01

### Ethics committee reference number

15-152-92

## 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

The number of episodes of crying

### Timepoint

24 hours on days 7, 14, 21 and 28

### Method of measurement

questionnaire

## Secondary outcomes

1

### Description

Crying time

### Timepoint

24 hours on days 7, 14, 21 and 28

### Method of measurement

questionnaire

## Intervention groups

1

### Description

Case Groups: 5 drops once daily probiotic drug treatment PdyLakt for 28 days and recommended technique for reducing colic, including voice and singing soothing, rhythmic rocking motion, walking, mild tremor and ...

### Category

Treatment - Drugs

2

### Description

Control group : only recommend techniques for reducing colic, including voice and singing soothing, rhythmic rocking motion, walking, mild tremor and ...

### Category

Behavior

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Arak AmirKabir Hospital

#### Full name of responsible person

Dr. Fatemeh Dorreh

#### Street address

Arak, Street RahAhan, Amir Kabir Hospital

#### City

Arak

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice Chancellor Arak University of Medical Sciences

#### Full name of responsible person

Dr. Mohammad Rafiee

#### Street address

School of Medicine

#### City

Arak

### Grant name

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Vice Chancellor Arak 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**  
Arak University of Medical sciences  
**Full name of responsible person**  
Dr. Fatemeh Dorreh  
**Position**  
Pediatrician  
**Other areas of specialty/work**  
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Dorreh.f@arakmu.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Dr. Fatemeh Dorreh  
**Position**  
Pediatrician

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### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr. Fatemeh Dorreh

#### Position

Pediatrician

#### Other areas of specialty/work

#### Street address

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## 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*