

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

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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 Pdulakt 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
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Pediatrician
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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