

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of probiotic compared with placebo in decreasing the duration of crying in infants with colic

Protocol summary

Summary

Objectives: To investigate the effect of probiotic compared with placebo in decreasing the duration of crying in infants with colic. Design: A single blind randomized clinical trial. Setting and conduct: The eligible infants with colic referred to pediatric clinic of Kashan Shahid Beheshti Hospital will be enrolled into the trial. Inclusion criteria: Well babies aged 1-3 months, Having Wessel criteria, Birth weight more than 2500 grams, Gestational age of 37-42 weeks, 5-minute Apgar score more than 7. Exclusion criteria: Chronic gastrointestinal diseases, Immune deficiency, A history of antibiotic or probiotics therapy, Acute disease, Allergies to materials used in the study. Intervention group: Pedilact 5 drops daily for 21 days. Control group: Placebo 5 drops daily for 21 days. Primary outcome: Duration of infantile crying in 24 hours before the intervention and 7th, 14th and 21th days after intervention through the recording of crying time by mother.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031611145N16**

Registration date: **2015-12-05, 1394/09/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-05, 1394/09/14

Registrant information

Name

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 5554 0026

Email address

sharif_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic compared with placebo in decreasing the duration of crying in infants with colic

Public title

The effect of probiotic in treatment of infantile colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Well babies aged 1-3 months; Having Wessel criteria; Birth weight more than 2500 grams; Gestational age of 37-42 weeks; 5-minute Apgar score more than 7; Parental consent Exclusion criteria: Chronic gastrointestinal diseases; Immune deficiency; A history of antibiotic or probiotics therapy; Acute disease; Allergies to materials used in the study; Lack of parental involvement

Age

From **1 month** old to **3 months** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Kashan University of Medical Sciences

Street address

Contact details : Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

City

Kashan

Postal code**Approval date**

2015-11-19, 1394/08/28

Ethics committee reference number

IR.KAUMS.REC.1394.110

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 infantile crying in 24 hours

Timepoint

Before the intervention and 7th, 14th and 21th days after intervention

Method of measurement

Recording of crying time by mother

Secondary outcomes

empty

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

Intervention group: Pedilact 5 drops daily for 21 days

Category

Treatment - Drugs

2**Description**

Control group: Placebo 5 drops daily for 21 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Dr. Mohammad Reza Sharif

Street address

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd, Kashan, Iran

City

Kashan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

City

Kashan

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, Kashan 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Sharif

Position

Associate Professor, Pediatric Infectious Diseases
Subspecialist

Other areas of specialty/work**Street address**

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Subspecialist

Other areas of specialty/work**Street address**

Kashan University of Medical Sciences, Ghotbe

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