Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
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Dr. Mohammad Reza Sharif
Position
Associate Professor, Pediatric Infectious Diseases Subspecialist
Other areas of specialty/work
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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