Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effectiveness of probiotic Lactobacillus reuteri and Placebo in reducing the time of restlessness in infants with infantile colic

Protocol summary

Summary

Infantile colic is one of the most parental complaints in the first few months of life and sometimes it causes anxiety in family. As the pathophysiology of colic has been not known hence there is no efficient way for therapy. New researches have shown that changes in the micro flora can be revealed the symptoms of colic. The aim of this study is the effect of probiotic Lactobacillus Reuteri on the time of fuss and crying in colicky infant. At least 30 infants in the single-blind trial, the inclusion criteria (infants 15 to 60 days...) and exclusion (of milk...) are selected. Then for 5 to 7 days five drops of placebo with label no.1 will be tried. We call the parents twice a day and check for the restlessness times. Then the drug with label no.2 (Bio Gaia drop that contains American type culture collection strain 55730 Lactobacillus Reuteri) will be started with 5 drops daily for two weeks. The mean of restlessness times before and after therapy will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012713489N2**
Registration date: **2014-07-04, 1393/04/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-04, 1393/04/13

Registrant information

Name

Zahra Akbarian Rad

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 8284

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Babol University of Medical Sciences.

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness of probiotic Lactobacillus reuteri and Placebo in reducing the time of restlessness in infants with infantile colic

Public title

Effect of probiotic in infantile colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Restless infants 15 to 60 days of age;With birth weight greater than 2500 g; Breast feeding; No signs or symptoms of chronic disease in history and initial examination; Normal urine analysis; Based on the criteria crying and agitation vessels at least 3 hours a day and more than 3 days a week Exclusion criteria: Use dry milk; use of antibiotics; Taking painkillers or carminative; chronic illnesses in infants

Age
From **15 days** old to **2 months** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Other
Other design features
At first drug and placebo will be prepared by physician’s assistant in similar vials and will be named with the labels 1 and 2. Physicians will give the drug and the placebo to patient. During 5-7 days, assistant calls the parents twice a day. Then we start with label 2 and record times of restlessness.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences.
Street address
Keshavarz street, Babol University of Medical Sciences
City
Babol
Postal code
Approval date
2013-04-21, 1392/02/01
Ethics committee reference number
2306/30/ژ/پ

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
Restlessness Times
Timepoint
Intervention every day starting two weeks after the intervention
Method of measurement
clinical

Secondary outcomes

empty

Intervention groups

1

Description
Probiotic Lactobacillus reuteri (American Type culture collection Strain 55730) produced by BioGaia company 5 drops orally,every days. until the day 14 of treatment.
Category
Treatment - Drugs

2

Description
Placebo,(distilled water) 5 drops orally every day for 5-7 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Aiatollah Rohani Hospital
Full name of responsible person
Yalda Taghipour
Street address
Ganjafroz street, Aiatollah Rohani Hospital
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Babol University of Medical Sciences
Full name of responsible person
Amrollah Mostafazadeh
Street address
Ganjafroz street, Babol University of Medical Sciences
City

Babol

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,Babol 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

Babol University of Medical Sciences

Full name of responsible person

Zahra Akbarian Rad

Position

Assistant professor/ Neonatologist

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