

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

z.akbarian@mubabol.ac.ir

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/پ/ز

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