Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation the effects of probiotics on infantile colic in breastfed colicky infants

Protocol summary

Summary

This research will be conducted as a single-blind randomized clinical trial on infants admitted to the Clinic's pediatric gastroenterology in Bouali Sina Hospital of Sari, Iran, who Will be diagnosed with infantile colic by pediatric gastroenterologist. Patients will be divided randomly into two case and control groups.Each group contains 50 patients. random number table was used. The control group will receive a placebo and the case group will be treated orally by Biogaia probiotics drop (containing L. reuteri making Ferring Germany and by Iran Dayatb) for 21 days. Probiotic drops in the intervention group Biogaia (containing Lactobacillus reuteri will prepared from Ferring Pharmaceuticals Co., Germany, by Daya Teb Co., Iran) will be orally administered daily with a volume of 5 drops, for 21 days. Placebo drops will be produced quite similar to the original drug, in terms of shape, size and color. hugging and correct way of breastfeeding will be taught identically in both case and control groups. Clinical assessment of the patients will be done on the first day of drug administration, day 7, day 14, day 21. on a weekly basis mothers will record the dosage and strain of Biogaia probiotics drop, as well as daily crying time tables .the whole context will be evaluated weekly by statistician. The sample size will be estimated to be 36 for each group, and finally was taken 50 samples for each group by considering the possibility of aberration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082829573N1**
Registration date: **2016-09-19, 1395/06/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-19, 1395/06/29

Registrant information

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Name of organization / entity
Torbat Heydariyeh University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor Of Research, Mazandran University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effects of probiotics on infantile colic in breastfed colicky infants

Public title

Investigation the effects of probiotics on infantile colic in breastfed colicky infants

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria for infants : age between 15 and 120 days; breastfeeding; failure to use of antibiotics; crying lasting for 3 hours or more than 3 hours per day, three days or more than 3 days per week, 5) birth weight between 2500 and 4000 gram. Exclusion criteria for infants leading to leave the study during the review period involved: start to consume powdered milk; taking antibiotics; definitive diagnosis for other causes of infant pain; the unwillingness of parents to continue the study; underlying disease; detection of and disease in patients in 6 months of age that mimics the symptoms of infantile colic.
Age
From **15 days** old to **4 months** old
Gender
Both

Phase
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
The Ethics Committee of Mazandran University of Medical Science
Street address
Mazandran University of Medical Science
City
Sari
Postal code
Approval date
2012-02-08, 1390/11/19
Ethics committee reference number
1390-11-19

Health conditions studied

1

Description of health condition studied
Infantile Colic
ICD-10 code
XI
ICD-10 code description
Diseases of the digestive system

Primary outcomes

1

Description
Cried Average in Week
Timepoint
3 Time
Method of measurement
Check List

Secondary outcomes

empty

Intervention groups

1

Description
The case group : Biogaia probiotics drop (containing L. reuteri making Ferring Germany and by Iran Dayatb) for 21 days.
Category
Treatment - Drugs

2

Description
control group: placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bouali Sina Hospital
Full name of responsible person
Street address
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor Of Research,Mazandran University of Medical Science

Full name of responsible person
Abolghasem Ajami
Street address
School of Medicine, Mazandaran University of Medical Sciences
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor Of Research,Mazandran University of Medical Science
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
Mazandran University of Medical Science
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Person responsible for scientific inquiries

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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