

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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

Name

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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, Mazandran 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

Full name of responsible person

Hasan Karami

Position

Associate Professor of Pediatrics

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bouali Sina Hospital

Full name of responsible person

Hamed Rohanizade

Position

Md,pediatrics, Pediatrics Department

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Torbat Heydariyeh University of Medical Sciences

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Maryam Tatari

Position

Academic staff

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Web page address**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*