

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Effect Of Probiotic And Placebo In Infantile Colic Adouble Blind Clinical Trail

Protocol summary

Summary

This randomized, doubleblind study was performed on 50 breastfed infants who were consecutively recruited from children medical center. All infants were diagnosed with infantile colic according Wessel's criteria: episodes of fussy crying lasted _3 hours a day and episodes _3 days in the 1 week before enrollment. Exclusion criteria were clinical evidence of chronic illness or gastrointestina disorders, intake of probiotics and/or antibiotics in the week preceding recruitment, and formula-feeding. Befor the start, and written informed consent was obtained from parents before inclusion of the infants. Colicky infants were randomly assigned to receive BioGaia drop or placebo. The bottles were coded and blinded by the study statistician for both the participants and for the physicians, and the code was revealed to the investigators once recruitment, data collection and all laboratory and statistical analyses were complete. At enrollment (day 0), parents were interviewed about gestational age, type of delivery, birth weight, presence of gastrointestinal disease, and crying time. Medical examinations were performed, and growth parameters were recorded at baseline and day 21. Parents were asked to fill in a structured diary to record the daily crying time (minutes), stool characteristics and frequency, and any adverse effects observed on each day of the study. A general linear model for repeated measures was used to assess differences in growth parameters between groups at the different time points (day 0 -21). Follow-up visits were performed by the same pediatrician on day 7 and 14 and 21.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204019353N1**

Registration date: **2012-06-02, 1391/03/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-06-02, 1391/03/13

Registrant information

Name

Fatemeh Farahmand

Name of organization / entity

Tehran Univercity Of Medical Siences

Country

Iran (Islamic Republic of)

Phone

+98 21 6644 9595

Email address

ffarahmand@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Probiotic And Placeb Have Brought For US With Out Any Charge

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Of Probiotic And Placebo In Infantile Colic Adouble Blind Clinical Trail

Public title

Effect Of Probiotic In Infantile Colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria; Term Infant; Birth Weight 2500- 4000 gr; Breast Milk Feeding; Age 3-16 Weeks ; Exclusion Criteria; Use Of Antibiotic; Use Of Probiotic During Weeks Ago; Any Kind Of Gastro Intestinal Disease

Age

From **1 year** old to **4 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University Of Medical Sciences

Street address

Qodes Street Boulvar Keshavarze

City

Tehran

Postal code

Approval date

2012-03-10, 1390/12/20

Ethics committee reference number

45323

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 Induction And Then Daily

Method of measurement

Documentation Of Crying Time BY Mother

Secondary outcomes

1

Description

Weight

Timepoint

Day Of 7; 14; 21

Method of measurement

Scale

Intervention groups

1

Description

Biogua 5 Drop Per Day Fore 21 Days

Category

Treatment - Drugs

2

Description

Placebo 5 Drop per Day for 21 Days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center

Full name of responsible person

Dr Azizollah Yousefi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ferring Pharmaceuticals

Full name of responsible person

Foroozan Torki

Street address

Ferring Iran No.47/West Farzan Street/Africa Ave/
Tehran 1687 /Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ferring Pharmaceuticals

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

Children Medical Center

Full name of responsible person

Dr Azizollah Yousefi

Position

Pediatric Gastroenterology Flow

Other areas of specialty/work

Street address

Children Medical Center 62 Gharib St 14144 Tehran
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+98 21 6692 4545

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dra_yusefi@yahoo.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Children Medical Center

Full name of responsible person

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Position

pediatric Gastro Enterology Flow

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