

# 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  
Iran

**City**

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**Postal code**

**Phone**

+98 21 6692 4545

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**Email**

dra\_yusefi@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

pediatric Gastro Enterology Flow

**Other areas of specialty/work**

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dra\_yusefi@yahoo.com

**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*