Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Bifidobacterium Animalis Spp. Lactis oral suspension effect on crying/fussing time and changes of gut microbiota in formula-fed infants with colic: A Double blind randomized clinical trial

Protocol summary

Study aim

the aim of present study is to evaluate Bifidobacterium lactis effectiveness in treatment of infantile colic in formula fed infants. markers such as length growth, weight gain, defecation and nine different species of fecal bacteria, bifidobacterium , Lactobacilli, Roseburia, Collinsella, Faecalibacterium, Enterobacteriaceae, Akkermansia, Bacteroides and Prevotella are measured before and 28 days after treatment. crying/fussing is evaluated weekly for four weeks

Design

participants are randomly assigned to two arms with 25 participant each. randomization and concealment are performed with distance randomization program accessed from: https://www.sealedenvelope.com

Settings and conduct

the study is performed at outpatient clinic of teaching hospitals of Shahid Rajjai of Tonekabon and Imam Sajjad of Ramsar. Participants are blinded with Placebo, technician is used to assigned drugs to participant to blind care givers.

Participants/Inclusion and exclusion criteria

inclusion criteria: diagnosis of colic based on ROME IV criteria less than 7 weeks of age exclusive formula feeding Exclusion criteria: low birth weight, prematurity, immunodeficiency, food allergy, heart or gastrointestinal disease disease, fever or infectious disease, use of products altering gut microbiota, neurological disease, GERD, congenital malformation, genetic disease.

Intervention groups

participants assigned to treatment group receive five drops of BB Care (Zist takhmir, Iran) probiotic oral suspension containing B. lactis 10^8 CFU four times daily. Placebo group receive oral suspension similar to BB Care production with exception that it contains no B. lactis. Placebo is purchased from Zist takhmir Company, Iran.

Main outcome variables

Crying/fussing of infant, amount of bifidobacterium , Lactobacilli, Roseburia, Collinsella, Faecalibacterium, Enterobacteriaceae, Akkermansia, Bacteroides و Prevotella in fecal samples

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170201032346N3**
Registration date: **2019-03-14, 1397/12/23**
Registration timing: **prospective**

Last update: **2019-03-14, 1397/12/23**
Update count: **0**

Registration date

2019-03-14, 1397/12/23

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 91155226108

Email address

firoozihosein@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Bifidobacterium Animalis Spp. Lactis oral suspension effect on crying/fussing time and changes of gut microbiota in formula-fed infants with colic: A Double blind randomized clinical trial

Public title
Evaluation of Bifidobacterium Animalis Spp. Lactis oral suspension effect on crying/fussing time and changes of gut microbiota in formula-fed infants with colic
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
exclusive formula feeding less than 7 weeks of age diagnosis of colic based on ROME IV criteria accepting informed consent
Exclusion criteria:
birth weight lower than 2500grams preterm birth (Gestational age<37 weeks) five minute Apgar score <7 breast feeding Central venous catheter severe medical condition valvular heart disease prematurity reduction in growth or weight reduction of more than 100gram from birth to the last measurement neurological disease known of suspected food allergy gastroesophageal reflux disease Probiotic, prebiotic, antibiotic or acid suppressing agents in the past two weeks history of fever or infectious disease in the past two weeks progressive systemic infection congenital infection chronic bowel disease, e.g. cystic fibrosis and primary pancreatic insufficiency primary or secondary digestive tract malformations, e.g. esophageal atresia, intestinal atresia, short bowel syndrome, malrotation metabolic disease genetic and chromosomal disease primary or secondary immunodeficiency syndrome suspecting noncompliance or caregiver's inability to act in accordance to the given protocol previous participation in medical research
Age
To **49 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
participant are randomized with Distance randomization method. two groups of 25 patients are assigned to treatment or placebo group. each patient is assigned to a unique code provided by Distance randomization service from www.sealedenvelope.com.
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo are provided by the company producing the product. in terms of appearance drug and placebo are identical. caregivers prescribe the drug. the research technician is assigned to lead two arms of study based on patient's assigned group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ramsar Campus, Mazandaran University of Medical Sciences
Street address
No.20, Taleghani Ave, Ramsar
City
Ramsar
Province
Mazandaran
Postal code
4691786953
Approval date
2019-03-12, 1397/12/21
Ethics committee reference number
IR.MAZUMS.RIB.REC.1397.001

2

Ethics committee
Name of ethics committee
Ethics committee of Ramsar Campus, Mazandaran University of Medical Sciences
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Province
Mazandaran
Postal code
4691786953
Approval date
2019-03-12, 1397/12/21
Ethics committee reference number
IR.MAZUMS.RIB.REC.1397.002

Health conditions studied

1

Description of health condition studied
Infantile colic, probiotic, intestinal dysbiosis, microbiota, bifidobacterium lactis
ICD-10 code
R10.4
ICD-10 code description
R10.4

Primary outcomes

1

Description
amount of infant Crying/fussing expressed in minutes
Timepoint
before and at 7, 14, 21 and 28 days after initiation of intervention
Method of measurement
according to Barr diaries

2

Description
fecal microbiota of infants
Timepoint
before and 28 days after the initiation of the intervention
Method of measurement
16s rRNA qPCR and Pyrosequencing

Secondary outcomes

1

Description
weight gain
Timepoint
before and 28 days after the intervention
Method of measurement
scale

2

Description
defecation, times per day
Timepoint
prior and 0, 7, 14, 21 and 28 days after the initiation of intervention
Method of measurement
questionnaire

3

Description
length growth
Timepoint
before and 28 days after the intervention
Method of measurement
متر

Intervention groups

1

Description
Intervention group: the product which is used in this study is BB Care (Zist takhmir, Iran) oral suspension which contain 1x 10^8 CFU per milliliter. patients are advised to take 5 drops, four times daily for 28 days
Category
Treatment - Drugs

2

Description
Control group: purchased placebo from the probiotic producing company (Zist Takhmir, Iran) is used for 28 days. 5 drops are given four times daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajaei hospital of Tonekabon
Full name of responsible person
Firouzi Hossein
Street address
Rajaei hospital, Emam Khomeini Ave., Tonekabon Mazandaran. Mazandaran.
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2

Recruitment center
Name of recruitment center
Imam Sajjad Hospital of Ramsar City
Full name of responsible person
Firouzi Hossein
Street address
Mazandaran Province, Ramsar, Motahari Street,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ramsar Campus, Mazandaran University of Medical Sciences
Full name of responsible person
Davood Farzin
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ramsar Campus, Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ramsar Campus, Mazandaran University of Medical Sciences
Full name of responsible person
Firouzi Hossein
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Email

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all collected deidentified data for primary and secondary outcome measures are going to be shared

When the data will become available and for how long

after publishing the study, data are going to be available

To whom data/document is available

data are going to be available to all researchers and clinician irrespective to their employment sector

Under which criteria data/document could be used

permission are granted upon request for secondary and meta-analysis

From where data/document is obtainable

requests are gathered through principle researcher's e-mail address

What processes are involved for a request to access data/document

upon verification of request and reason data are given in three month.

Comments