Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of lactobacillus GG on gastrointestinal symptoms of infants with cow`s milk protein allergy

Protocol summary

Summary

In a randomized, double-blind, placebo-controlled study,thirty two breastfed infants aged 1 months to 12 months with cow`s milk protein allergy will be enrolled in randomised control trial in which they receive lactobacillus GG or placebo for one month. Clinical symptoms of gastrointestinal function (vomiting, colic, rectal bleeding and diarrhea), and baseline characteristics (head circumference, body length and weight) will recorded at the beginning, the end of first and third months of treatment .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301314976N2**
Registration date: **2013-05-07, 1392/02/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-07, 1392/02/17

Registrant information

Name
Hamid Ahanchian
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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+98 51 3801 2469
Email address
ahanchianh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source
Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2010-01-03, 1388/10/13

Expected recruitment end date

2011-03-04, 1389/12/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lactobacillus GG on gastrointestinal symptoms of infants with cow`s milk protein allergy

Public title

A new symbiotic may improve weight gain in infants with cow’s milk allergy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-12 months-old infants with the clinical symptoms of cow's milk protein allergy including rectal bleeding, diarrhea, vomiting and evidences of colitis; a good general condition, breast milk feeding and cow's milk consuming mother. The infants are excluded from the study if they had a known immune deficiency, gastro intestinal disease, positive stool culture, coagulopathy or are receiving any type of antibiotic therapy.

Age

To **1 year** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

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
Mashhad University of Medical Sciences Ethics Committee

Street address
Ghoreish bulding, Daneshgah street

City
Mashhad

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
87357

Health conditions studied

1

Description of health condition studied
Cow milk protein allergy

ICD-10 code
K90.4

ICD-10 code description
Malabsorption due to intolerance to: carbohydrate-fat-protein-starch

Primary outcomes

1

Description
Severity of gastrointestinal symptoms

Timepoint
At the beginning of the study, 3 months after intervention

Method of measurement
The number of vomiting, colic, rectal bleeding and diarrhea

Secondary outcomes

1

Description
weight

Timepoint
At the beginning of the study, 3 months after intervention

Method of measurement
Gram

2

Description
head circumference

Timepoint
At the beginning of the study, 3 months after intervention

Method of measurement
centimeter

3

Description
body length

Timepoint
At the beginning of the study, 3 months after intervention

Method of measurement
centimeter

Intervention groups

1

Description
The control group received placebo without probiotics which are match for size, shape, and volume of contents and manufactured by the same company, daily for 4 weeks

Category
Placebo

2

Description
The study group will receive a synbiotic containing 1 billion Colony Forming Units (CFU) of ProtexinR Restore: a mixture of Lactobacillus casei, Lactobacillus rhamnosus, Streptococcus thermophilus, Bifidobacterium breve, Lactobacillus acidophilus, Bifidobacterium infantis, Lactobacillus bulgaricus and FOS (Protexin healthcare, Somerset, United Kingdom), in the form of freeze dried powder will administer daily for 4 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital

Full name of responsible person
Dr Hamid Ahanchian

Street address
Pediatric Allergy department, Ghaem hospital, Ahmad Abad Blvd, Mashhad, Iran

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person
Associate Professor Mohsen Tafaghodi

Street address
Ghoreishi bulding, Daneshgah street

City
Mashhad

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Mashhad University of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ghaem hospital

Full name of responsible person
Hamid Ahanchian

Position
Assistant professor

Other areas of specialty/work

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Person responsible for updating data

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Position
Assistant professor

Other areas of specialty/work

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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