Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Investigation of the Effect of Lactobacillus rhamnosus on the clinical course of infants with allergic proctocolitis .

Protocol summary

Study aim
The aim of this study is to assess the effect of Lactobacillus rhamnosus in treatment of patients with allergic proctocolitis.

Design
Clinical trial with control group, with parallel group, double blinded, phase 3 investigation of 20 patients. Randomised using the RAND function of Microsoft Excel.

Settings and conduct
This multi-center trial will be performed involve 1 to 24 month-old infants diagnosed with allergic proctocolitis. Patients will be randomly divided in to two groups. Infants in both groups will receive elimination of allergen from diet. Infants in the control group will receive placebo and infants in the intervention group willreceive probiotic Lactobacillus rhamnosus .

Participants/Inclusion and exclusion criteria
Infants between the ages of 1 to 24 months, diagnosed with allergic proctocolitis (visible or occult blood in stool) from Bahrami Pediatric Hospital and The Medical Center for Children Hospital, will be enrolled to the study. Infants between the ages of 1 to 24 months, diagnosed with bacterial gastroenteritis and patients who have already used probiotics will be excluded from participation . Lack of consent from parents of the infant will result in exclusion.

Intervention groups
The standard treatment for allergic proctocolitis , in form of dietry exclusion of the allergen from the mother and the subject`s diet , will be undertaken in all participants . In the control group placebo, and in the treatment group Lactobacillus rhamnosus will be administered.

Main outcome variables
Elimination of blood, visible or occult, from the patient's stools.

General information

Reason for update

Acronym
CMPA

IRCT registration information
IRCT registration number: **IRCT20140830018971N6**
Registration date: **2021-02-01, 1399/11/13**
Registration timing: **prospective**

Last update: **2021-02-01, 1399/11/13**
Update count: **0**

Registration date
2021-02-01, 1399/11/13

Registrant information

Name
Kambiz Eftekhari

Name of organization / entity
Tehran University of Medical Science

Country
Iran (Islamic Republic of)

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+98 21 7301 3000

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k-eftekhari@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the Effect of Lactobacillus rhamnosus on

the clinical course of infants with allergic proctocolitis .

Public title
The effect of probiotics on cow milk allergy .
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infants between the ages of 1 to 24 months diagnosed with allergic proctocolitis because of hematochezia. Infants between the ages of 1 to 24 months diagnosed with allergic proctocolitis because of occult blood.
Exclusion criteria:
Infants diagnosed with lactose malabsorbtion. Infants diagnosed with bacterial gasrtoenteritis. Infants treated with probiotics.
Age
From **1 month** old to **24 months** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Using randomised size 4 and 2 allele blocks ,the subjects will be divided in to group A placebo and group B treatment . The below model will be used to distinguish each group: AABB-ABBA-ABABA-BBAA-BABA-BAAB,.....
Blinding (investigator's opinion)
Double blinded
Blinding description
Since the subjects of the study are infants, they will not be aware of the type therapy randomised to them . Furthermore, the investigators will be blinded to the randomisation process. Thus, making this a double-blinded study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of medical science
Street address
Ansaralhussein Ave., Kiaee Ave., Damavand Ave.
City
Tehran
Province
Tehran
Postal code
4499116417
Approval date
2021-01-21, 1399/11/02
Ethics committee reference number
IR.TUMS.CHMC.REC.1399.187

Health conditions studied

1

Description of health condition studied
Infantile allergic proctocolitis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Visible or occult blood in the stool.
Timepoint
Day 5 and 14 from start of the treatment.
Method of measurement
Stool results.

Secondary outcomes

empty

Intervention groups

1

Description
The intervetion group will receives 10 drops of Ramnoflor solution orally a day for 8 weeks, containing LGG 5*10^10 , from Farabiotic Pharmaceuticals in Iran; the control group will receive placebo without LGG.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahrami hospital
Full name of responsible person
faeze ghanaati
Street address

Ansaralhussein Ave., Kiaee Ave., Damavand Ave

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Phone
+98 21 7759 2300

Email
faezeghanaati@gmail.com

2

Recruitment center

Name of recruitment center
Children`s medical center

Full name of responsible person
faeze ghanaati

Street address
Keshavarz Blvd

City
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Province
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Postal code
1419733151

Phone
+98 21 6147 9000

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Faeze Ghanaati

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available