

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 will receive 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 dietary 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)

Phone

+98 21 7301 3000

Email address

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*10¹⁰ , 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

Tehran

Postal code

1419733151

Phone

+98 21 6147 9000

Email

faezeghanaati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

faeze ghanaati

Street address

Ansaralhussein Ave., Kiaee Ave., Damavand Ave

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

faeze ghanaati

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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