

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

evaluation and comparison of the effect of diet with or without probiotic on the breastfeed infants proctocolitis

Protocol summary

Study aim

Evaluation of the effect of diet with or without probiotic on the breastfeed infants proctocolitis

Design

Randomized parallel group trial; double blinded, on 30 patients; randomization is done by random number table

Settings and conduct

In this randomized double blinded clinical trial, newborns aging to 12 months with cow's milk protein allergy that referred to pediatric center of Tehran University of Medical Science will be evaluated. 30 patients will be divided to test and control groups by random number tables. In all patients all of cow milk products will be inhibited. Calcium supplement and vitamin D would be prescribed for mothers. The test group would be prescribed with probiotic containing lactobacillus rhamnosus. The control group would be prescribed with placebo for 4 weeks. Clinical symptoms including irritability, number of defecation in every week, mucus in stool, blood in stool, time of pain in a week, would be evaluated for 4 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of newborn to 12 months; cow milk protein allergy; breast feed Exclusion criteria: taking probiotic and prebiotic in the last two months; taking antibiotic in the last two weeks; systemic infection

Intervention groups

Test group: taking probiotic Control group: taking water

Main outcome variables

Elimination of clinical symptoms of allergy; negative white blood cells in stool

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210817052216N1**

Registration date: **2021-10-02, 1400/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-02, 1400/07/10**

Update count: **0**

Registration date

2021-10-02, 1400/07/10

Registrant information

Name

Shivasadat Khalifehsoltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8839 0538

Email address

shiva.khalifeh.ped@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation and comparison of the effect of diet with or without probiotic on the breastfeed infants proctocolitis

Public title

effect of probiotic on inflammatory diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age newborn to 12 months cow milk protein allergy
breast fed

Exclusion criteria:
taking probiotic/prebiotic in last two months taking
antibiotic in the last two weeks existing systemic
infection in clinical examination positive stool culture
fever disease hirschsprung coagulopathy systemic
disease formula fed

Age
From **5 days** old to **12 months** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research we will use simple randomization by random number table to assign patients to test and control groups. To avoid disparity between group sizes, we will use replacement randomization. If the disparity exceeded the preset criterion of 3, we will generate another randomization list using simple randomization until we achieve a balanced group size. Randomization would be concealed using sequentially numbered, sealed, opaque envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
The A bottle contain probiotic and the B bottle contains water. The bottles are completely similar and would be given to the clinician. He/she and also the statistic analyzer does not know the relation between the alphabet and the content of bottles.

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
No. 7, Gharib Ave., Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1414744978

Approval date
2020-07-27, 1399/05/06

Ethics committee reference number
IR.TUMS.CHMC.REC.1399.094

Health conditions studied

1

Description of health condition studied

Caws milk protein allergy

ICD-10 code

Z91.011

ICD-10 code description

Allergy to milk products

Primary outcomes

1

Description

Elimination of clinical symptoms of allergy; negative white blood cells in stool

Timepoint

Evaluation of stool WBC in the start and after 4 weeks

Method of measurement

Stool Exam

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: probiotic droplet containing lactobacillus ramosous. Every 5 droplet conatins 5*10*8 cells of lipofilized lactobacillus ramosous that would be prescribed for 1 month.

Category

Treatment - Drugs

2

Description

Control group: 5 droplet of distilled water would be prescribed daily for 1 month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric center of Tehran University of Medical Science

Full name of responsible person

Shivaasadat Khalifehsoltani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shivaasadat Khalifehsoltani

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Tehran University of Medical Science

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

Shivasadat Khalifehsoltani

Position

Fellow

Latest degree

Specialist

Other areas of specialty/work

Gastroinestinology

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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Other areas of specialty/work

General Practitioner

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Person responsible for updating data

Contact

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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