Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of the therapeutic effect of probiotics in children with allergy to cow's milk protein

Protocol summary

Summary

In this randomized, single-blind clinical trial, infants younger than year with allergy to cow's milk protein referred to pediatric gastroenterology clinic of Bouali Sina Hospital of Sari are evaluated. In case of consuming probiotics and prebiotics within 2 months and receiving antibiotics within 2 weeks patients are excluded. Patients are randomly divided into two intervention and control groups with table of random numbers. Limitation of dairy cattle consumption for mother and infants are applied. For the intervention group, in addition to diet protocol, one sachet Protexin probiotic made by Health care co. is administered daily for 4 weeks and the control group receives the same package containing Aptamil Pepti Junior formula one sachet per day for 4 weeks. At the beginning of the study, stool cultured and analysis and fecal calprotectin are performed for all patients and then at second, 4th, 8th, 12th and 16th week, WBC and RBC level and occult blood and fecal calprotectin are measured. At 4th and 16th week, stool culture is done to determine the intestinal flora. During the first 16 weeks of the treatment, the number of stools per week, mucoid stools per week, number of stool bleeding in week, pain in week are recorded and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017043033595N2**
Registration date: **2017-07-02, 1396/04/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-02, 1396/04/11

Registrant information

Name
Hassan Karami
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and Technology of Mazandaran University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-12-20, 1396/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the therapeutic effect of probiotics in children with allergy to cow's milk protein

Public title

The therapeutic effect of probiotics in children with allergy to cow's milk protein

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 1-12 months; cow's milk allergy
Exclusion criteria: consuming probiotics and prebiotics within 2 months, receiving antibiotics within 2 weeks,

evidence of systemic infection on physical exam, positive stool culture for pathogens; febrile infants; Hirschsprung's disease,; coagulopathy, systemic disease, consumption of formula

Age
To **12 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Moallem square, Sari, Iran

City
Sari

Postal code

Approval date
2017-06-13, 1396/03/23

Ethics committee reference number
IR.MAZUMS.REC.96.2123

Health conditions studied

1

Description of health condition studied
Adverse effects, not elsewhere classified

ICD-10 code
T78

ICD-10 code description
Allergy, unspecified

Primary outcomes

1

Description
Calprotectin

Timepoint
0, 2, 4, 8, 12, 16 weeks

Method of measurement
ELIZA

2

Description
Bacterial growth in culture

Timepoint
0, 4, 16 weeks

Method of measurement
Stool culture

3

Description
WBC, RBC and occult blood

Timepoint
0, 2, 4, 8, 12, 16 weeks

Method of measurement
Stool analysis

Secondary outcomes

1

Description
The number of stools per week

Timepoint
0, 2, 4, 8, 12, 16 weeks

Method of measurement
Interview with infant's Mother

2

Description
The number of mucoid per week

Timepoint
0, 2, 4, 8, 12, 16 weeks

Method of measurement
Interview with infant's Mother

3

Description
Number of blood in the stool per week

Timepoint
0, 2, 4, 8, 12, 16 weeks

Method of measurement
Interview with infant's Mother

4

Description
Pain duration in week (minute)

Timepoint

0, 2, 4, 8, 12, 16 weeks

Method of measurement

Interview with infant's Mother

Intervention groups

1

Description

The control group receives the same package containing Aptamil Pepti Junior formula one sachet per day for 4 weeks

Category

Placebo

2

Description

For the intervention group, in addition to diet protocol, one sachet Protexin probiotic made by Health care co. is administered daily for 4 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali Sina Hospital

Full name of responsible person

Street address

Bouali Sina Hospital, Pasdaran Boulevard, Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Ahmadali Enayati

Street address

Sari

City

Sari

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 of Mazandaran 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

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hassan Karami, MD

Position

Associate proffessor

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hassan Karami, MD

Position

Associate professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Sahar Borna

Position

Student

Other areas of specialty/work

Street address

Sari

City

Sari

Postal code

Phone

00

Fax

Email

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