

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Study the effects of probiotics in the prevention of antibiotic-associated diarrhea in children

Protocol summary

Summary

Researches inclined to use probiotics in order to prevent AAD so that they can achieve better compliance in completing the course of antibiotic therapy. The aim of this randomized, placebo-controlled, double-blind trial was to assess the efficacy of probiotic protexin for prevention of AAD. From May 2010 to November 2011, a total of 219 patients (aged 6 months to 14 years) with respiratory tract infection and/or otitis media who had begun receiving antibiotics were randomized to receive protexin or placebo for 7 days. Patients' mother recorded bowel frequency and stool consistency daily for 7 days. Control group receiving placebo quite similar to probiotics but without any effect of probiotic. Probiotic and placebo packages as a daily sachet for ten days for the patients are randomly and the code is recorded in a questionnaire. Parents are also given a questionnaire to give information about Patient, Stool consistency, Stools per day and the possible occurrence of fever, Vomiting and bloody diarrhea associated with antibiotics can reduce the risk of diarrhea. Until these issues in the event The patient should be excluded. Then at 3 and 7 days of antibiotic and probiotic or placebo, Presence Or telephone Information was obtained from parents and is recorded to be used in the final assessment. The primary outcome was the proportion of patients who developed AAD within 7 days of enrollment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205229828N1**
Registration date: **2012-07-09, 1391/04/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-09, 1391/04/19

Registrant information

Name

Rasoul Alimi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

8544633 8544643 و

Email address

alimir901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2011-11-21, 1390/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effects of probiotics in the prevention of antibiotic-associated diarrhea in children

Public title

Study the effects of probiotics in the prevention of antibiotic-associated diarrhea in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : Children 6 months to 14 years ; Due to

upper respiratory infection or ear infection ; Referred to in the first 24 hours of starting antibiotics Exclusion criteria: Severe infection or bacterial genaralyze ; Antibiotic treatment within 2 months before treatment ; Antibiotic prophylaxis; The use of probiotic products in recent months;Known immunodeficiency; Chronic intestinal infection; Acute and chronic diarrhea; Use more than one type of antibiotic treatment during the period; Heart or lung disease or severe renal, Lactase deficiency is known; viral gastroenteritis (rotavirus) ; Passing blood in the stool,Vomiting with diarrhea and severe dehydration;Incorrect or incomplete use of antibiotics ; failure to complete treatment course

Age

To **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **230**

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-Ghaem Hospital

Street address

parastar st.- Ahmedabad Avenue

City

Mashhad

Postal code

99199-91766

Approval date

2011-01-01, 1389/10/11

Ethics committee reference number

89454

Health conditions studied**1****Description of health condition studied**

Diarrhea

ICD-10 code

A09

ICD-10 code description

Other gastroenteritis and colitis of infectious and unspecified origin

Primary outcomes**1****Description**

Diarrhea

Timepoint

Over a period of more than three loose stools in 48 hours

Method of measurement

Question of the mother

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group receiving Probiotic packages As a daily Prvtsyn Sasht To ten days .Probiotics contain a billion or a phrase such as Sasht 10*9 live microorganisms that are considered for each patient is 10 to 10 days and The code is recorded in a questionnairer.Parents are also given a questionnaire to give information about Patient,Stool consistency,Stools per day and the possible occurrence of fever,Vomiting and bloody diarrhea associated with antibiotics can reduce the risk of diarrhea,Until these issues in the event The patient should be excluded.Then at 3 and 7 days of probiotic ,Presence Or telephone Information was obtained from parents and is recorded to be used in the final assessment.

Category

Treatment - Drugs

2**Description**

The control group received a placebo that are quite similar with probiotic. The control group receiving Placebo packages As a daily Prvtsyn Sasht To ten days .Placebo are considered for each patient is 10 to 10 days and The code is recorded in a questionnairer.Parents are also given a questionnaire to give information about Patient,Stool consistency,Stools per day and the possible occurrence of fever,Vomiting and bloody diarrhea associated with antibiotics can reduce the risk of diarrhea,Until these issues in the event The patient should be excluded.Then at 3 and 7 days of placebo ,Presence Or telephone Information was obtained from parents and is recorded to be used in the final

assessment.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr.ali khakshoor
Street address
parastar st., Ahmedabad Avenue
City
MASHHAD

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ali jafari
Street address
Ghaem hospital, parastar st., Ahmedabad Avenue
City
MASHHAD

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Name of organization / entity
Ghaem Hospital
Full name of responsible person
Simin Partovi
Position
Assistant Professor of Pediatrics
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
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Ali Jafari
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Gastroenterologist
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Person responsible for updating data

Contact

Name of organization / entity
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Other areas of specialty/work
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parastar st., Ahmedabad Avenue
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partovis@mums.ac.ir
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