Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Summary

Researchures inclined to use probiotics in order to prevent AAD so that they can achieve better compliance in completen 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 Sasht To 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 7days 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)
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8544633 8544643 و
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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 Prvtksyn 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 Prvtksyn 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

Full name of responsible person

Ali Jafari

Position

Gastroenterologist

Other areas of specialty/work

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Ghaem hospital, parastar st., Ahmedabad Avenue

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jafaria@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ghaem Hospital

Full name of responsible person

Simin Partovi

Position

Assistant Professor of Pediatrics

Other areas of specialty/work

Street address

parastar st., Ahmedabad Avenue

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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