Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the Effects of Synbiotic on Preventing Antibiotic Associated Diarrhea in children admitted in Imam Hosein Hospital in Isfahan City

Protocol summary

Study aim
The effects of Synbiotics on preventing Antibiotic Associated Diarrhea

Design
Clinical Trial with control group, with parallel groups, blinded, Ranomized

Settings and conduct
This study is done in Imam Hosein Hospital in Isfahan city. Admitted patients with 2 months to 14 years ages that are candidate for Antibiotic therapy are treated with Synbiotic or placebo. Drops with contents of Synbiotic or placebo are produced by pharmacology factory and special codes are allocated for each drop and researcher and patients do not have any information about drop contents. Treatment is started 24 hours after Antibiotic therapy and continue for 7 days after finishing Antibiotic therapy and patients are evaluated for presence of diarrhea every 3 days. Patients are followed for 21 days after finishing Antibiotic therapy.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) 2 months to 14 years age, 2) Admitted in Imam Hosein Hospital, 3) Candidate for Antibiotic therapy due to infection for equal and more than 5 days, 4) Parent's willingness Exclusion criteria: 1)Chronic or acute diarrhea before starting Antibiotics, 2) Recent Antibiotic therapy during last 2 months, 3) Recent prophylactic Antibiotic use, 4) Underlying diseases, 5) Central vein catheterization, 6) Recent use of probiotics

Intervention groups
Intervention group: Patients receiving Synbiotic 24 hours after starting Antibiotic therapy and continue 7 days after finishing treatment. Control group: Patients receiving Placebo 24 hours after starting Antibiotic therapy and continue 7 days after finishing treatment.

Main outcome variables
Number of defecation; Stool consistency; Incidence of diarrhea; Diarrhea duration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171119037543N2**
Registration date: **2018-02-03, 1396/11/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-03, 1396/11/14**
Update count: **0**

Registration date
2018-02-03, 1396/11/14

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 913 894 5212
Email address
m.goli@resident.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Effects of Synbiotic on Preventing

Antibiotic Associated Diarrhea in children admitted in Imam Hosein Hospital in Isfahan City

Public title
Synbiotic and Antibiotic Associated Diarrhea
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Children with 2 months to 14 years age Children who are admitted in Imam Hosein Hospital in Isfahan City Children who are candidate for Antibiotic therapies due to infections for equal and more than 5 days Parent's willingness to participating in this study
Exclusion criteria:
Acute or chronic diarrhea before starting Antibiotic Having Antibiotic therapy during last 2 months Having prophylactic Antibiotic treatment Having Clostridium Difficile Associated Diarrhea during last 3 months Having underlying gastrointestinal disease Having central vein catheterization Having history of using probiotics during last 7 days Having immune deficiency Having underlying cardiovascular disease Having sever malnutrition or sever illness Having long term use of medications with gastrointestinal effects
Age
From **2 months** old to **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The type of randomization in this study is Block Randomization. In this study, Synbiotic and placebo are produced in drop forms with same shapes by pharmacology factory and get to researchers. The factory allocates an special code for each drop and researcher and patients do not have any information about the contents of drops. A table is planned and the name of patient and his/ her drop code are registered. In analyzing time, these codes and drop contents are get from factory and data are analyzed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, researcher and patients do not have any information about contents of drops. Drops with Synbiotics and placebo are produced by pharmacology factory in same shape and special codes are allocated for each drop. The contents of drops are get from factory in analyzing time.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Science
Street address
Imam Hosein Hospital, Imam Khomeini Street
City
Isfahan
Province
Isfehan
Postal code
8195163381
Approval date
2017-05-22, 1396/03/01
Ethics committee reference number
IR.MUI.REC.1396.3.374

Health conditions studied

1

Description of health condition studied
Antibiotic Associated Diarrhea
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Number of defecation
Timepoint
Every 3 days after starting Antibiotic treatment to 21 days after finishing Antibiotic treatment
Method of measurement
Interview with parents

2

Description
Stool Consistency
Timepoint
Every 3 days after starting Antibiotic treatment to 21 days after finishing Antibiotic treatment
Method of measurement
Bristol Stool Scale questionnaire

3

Description

Incidence of diarrhea

Timepoint

Every 3 days after starting Antibiotic treatment to 21 days after finishing Antibiotic treatment

Method of measurement

Interview with parents

4

Description

Diarrhea duration

Timepoint

Every 3 days after starting Antibiotic treatment to 21 days after finishing Antibiotic treatment

Method of measurement

Interview with parents

Secondary outcomes

1

Description

Incidence of constipation

Timepoint

Every 3 days after starting Antibiotic treatment to 21 days after finishing Antibiotic treatment

Method of measurement

Interview with parents

2

Description

Presence of blood in stool

Timepoint

Every 3 days after starting Antibiotic treatment to 21 days after finishing Antibiotic treatment

Method of measurement

Interview with parents

Intervention groups

1

Description

Intervention group: Synbiotic powder (Protexin Restore), Starting 24 hours after starting Antibiotic therapy until 7 days after finishing Antibiotic therapy, One sachet daily, produced by Protexin Health Care Company

Category

Prevention

2

Description

Control group: Placebo in powder shape, Starting 24 hours after starting Antibiotic therapy until 7 days after finishing Antibiotic therapy, One sachet daily, produced by faculty of Pharmacy in Isfahan University of Medical Science

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein Hospital

Full name of responsible person

Hamid Rahimi

Street address

Imam Hosein Hospital, Imam Khomeini Street

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m.goli@resident.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian

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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

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mozhgan Goli

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Hamid Rahimi

Position
Associate Professor

Latest degree
Subspecialist

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Pediatrics

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Person responsible for updating data

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Name of organization / entity
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Position
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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