Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the therapeutic effect of synbiotics on acute diarrhea in admitted children aged between 6-24 months; A randomized double blind placebo controlled trial

Protocol summary

Study aim
Evaluating the therapeutic effect of synbiotics on acute diarrhea in admitted children aged between 6-24 months

Design
Pragmatic, Community based, Parallel groups, double blind, randomized controlled trial.

Settings and conduct
This study will be done in the digestive ward Aboozar hospital of Ahvaz. This study will be double blinded of interventions. Blinding technique will be samed in shape, color, size and taste in the study group.

Participants/Inclusion and exclusion criteria
Inclusion: Children with diarrhea age is 24 to 6 months; Patients with acute non-bacterial diarrhea; The duration of diarrhea is less than two days; Patients with moderate dehydration; Patients with acute non-bloody diarrhea; Exclusion: Patients with severe dehydration; Children who show no weight gain; Children who have taken antibiotics during diarrhea; Children who have severe vomiting; Children who have seizures.

Intervention groups
Intervention group: Synbiotic drop orally at dose of 5 drops/day, one time daily for 5 days

Main outcome variables
Reduced hospitalization time.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181231042190N1**
Registration date: **2019-02-27, 1397/12/08**
Registration timing: **prospective**

Last update: **2019-02-27, 1397/12/08**
Update count: **0**

Registration date
2019-02-27, 1397/12/08

Registrant information

Name
Azadeh Arefian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2620 2715

Email address
azadeh.aref@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-10, 1397/12/19

Expected recruitment end date
2019-06-20, 1398/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the therapeutic effect of synbiotics on acute diarrhea in admitted children aged between 6-24 months; A randomized double blind placebo controlled trial

Public title
Effect of synbiotics in treatment of diarrhea

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children with diarrhea whose age is 24 to 6 months. Patients with acute non-bacterial diarrhea. The duration of diarrhea is less than two days. Patients with moderate dehydration. Patients with acute non-bloody diarrhea. Patients who use breast milk. Patients who have not taken antibiotics over the past two weeks. Patients whose parents have signed a consent form.
Exclusion criteria:
Patients with severe dehydration. Children who show no weight gain. Children who have taken antibiotics during diarrhea. Children who have severe vomiting. Children who have seizures. Patients found in their stool samples have inflammatory cells. Patients with a history of a variety of metabolic diseases. Children with a history of blood disorders and anemia. Patients with a history of a variety of digestive diseases. Patients who use formula milk. Patients with acute bloody diarrhea.

Age
From **6 months** old to **24 months** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the 4-block method, individuals will be divided randomly into two equal groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients and nurses who prescribed medications to patients are blinded to the type of drugs. The main drug and placebo are the same in the terms of shape, size, taste and packaging. The physician that collect treatment outcomes will not be blinded allocation of interventions.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences.

Street address
Golestan street, Shahr Daneshgahi, Deputy of Research and Technology Development of Ahvaz Jondishapur University of Medical Sciences, Ahvaz.

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2018-09-21, 1397/06/30

Ethics committee reference number
IR.AJUMS.REC.1397.424

Health conditions studied

1

Description of health condition studied
Non infectious acute diarrhea

ICD-10 code
P78.3

ICD-10 code description
Noninfective neonatal diarrhea

Primary outcomes

1

Description
Time of Hospitalization

Timepoint
The duration of treatment

Method of measurement
The duration of hospitalization

Secondary outcomes

1

Description
Pharmaceutical allergy

Timepoint
The duration of treatment

Method of measurement
Clinical observation

Intervention groups

1

Description
Intervention group: Synbiotic drop orally at dose of 5 drops/day, one time daily for 5 days

Category
Treatment - Drugs

2

Description
Control group: Placebo drop orally at dose of 5 drops/day, one time daily for 5 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Abozar Hospital
Full name of responsible person
Dr. Azadeh Arefian
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Tohid Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Golestan street, Shahr Daneshgahi, Deputy of Research and Technology Development of Ahvaz Jondishapur University of Medical Sciences, Ahvaz.
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Azadeh Arefian
Position
Resident of Pediatrics
Latest degree
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Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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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
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available