

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+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

##### Street address

Tohid Boulevard

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

61357-15794

##### Phone

+98 61 3444 9003

##### Email

itc@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

دکتر مهران حکیم زاده

##### Street address

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

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

61357-15794

##### Phone

+98 61 3336 2414

##### Email

itc@ajums.ac.ir

##### 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

Medical doctor

##### Other areas of specialty/work

Pediatrics

##### Street address

Khuzestan Province, Ahvaz, Zeytun Karmandi, Tohid Blv. Aboozar Children's Hospital.

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

61375-15794

##### Phone

+98 61 3444 9003

##### Email

azadeh.aref@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr. Mehran Hakimzadeh

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Pediatrics

##### Street address

Khuzestan Province, Ahvaz, Zeytun Karmandi, Tohid Blv, Aboozar Children's Hospital

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

61357-15794

##### Phone

+98 61 3444 9003

**Email**

hakimzadeh-m@ajums.ac.ir

**Phone**

+98 61 3444 9003

**Email**

azadeh.aref@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Azadeh Arefian

**Position**

Resident of Pediatrics

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Zeytun Karmandi, Tohid Blv. Aboozar Children's Hospital

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61375-15794

**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