

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison of the effect of synbiotics and zinc in the treatment of acute diarrhea in children

#### Protocol summary

##### Study aim

Comparison of the effect of synbiotics and zinc in the treatment of acute diarrhea in children

##### Design

Clinical trial, With parallel group, Without blinding, On 80 patients. Rand function of Excel software was used for randomization.

##### Settings and conduct

This study was performed on children who were referred to the infectious ward of Qazvin Quds Hospital with a diagnosis of acute diarrhea. Patients are divided into two groups and group A will be given a sachet containing probiotics daily and group B will be given 5 mg of zinc gluconate syrup every six hours for 10-14 days. This study is performed without blinding.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Existence of acute diarrhea (watery or loose stools three or more times in 24 hours for less than 14 days) 2- Existence of mild dehydration and intermediate 3- Age 2-5 years 4- No antibiotic, zinc-containing compounds, Probiotics and synbiotics in the last 1 month Exclusion criteria: Children with chronic diarrhea (diarrhea over 14 days), bacterial diarrhea (presence of any number of white blood cells with or without red blood cells in fecal examination with abnormal stool culture), parasitic infections (such as Giardia and amoebae), dehydration Severe (more than 9%), abdominal distension, intestinal obstruction, comorbidities and underlying diseases such as malnutrition and diabetes.

##### Intervention groups

Group A will be given a sachet of probiotics and prebiotics dissolved in water daily. Group B will be given 5 mg of zinc gluconate syrup every six hours for 10-14 days

##### Main outcome variables

1- Determining the average number of daily diarrhea in children receiving synbiotics and zinc 2- Determining the average recovery time of diarrhea in children receiving

synbiotics and zinc 3- Determining complications in the group receiving synbiotics and zinc 4. Mean hospital stay in the group receiving synbiotics and zinc

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210523051375N1**

Registration date: **2021-09-16, 1400/06/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-09-16, 1400/06/25**

Update count: **0**

##### Registration date

2021-09-16, 1400/06/25

##### Registrant information

##### Name

banafshe samadpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3333 4807

##### Email address

rad2180@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-30, 1400/04/09

##### Expected recruitment end date

2022-06-30, 1401/04/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of synbiotics and zinc in the treatment of acute diarrhea in children

**Public title**  
Evaluation of the effect of synbiotics and zinc in the treatment of acute diarrhea

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Existence of acute diarrhea Existence of mild to moderate dehydration Not receiving antibiotics, zinc-containing compounds, probiotics and synbiotics in the last 1 month  
**Exclusion criteria:**  
Existence of severe dehydration Children with chronic diarrhea Bacterial diarrhea Ileus

**Age**  
From **1 year** old to **5 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients are assigned to two groups a and b using the balance block method (Balance block randomization). The size of each block is 4. Balanced randomization allocation method for participants in a randomized clinical trial study is the effect of synbiotics (group a) and zinc (group b) in reducing diarrhea in children . The tool is random allocation software.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Qazvin University of Medical

Science

**Street address**  
Valiasr Square, Shahid Beheshti Boulevard, Quds Hospital

**City**  
Qazvin

**Province**  
Qazvin

**Postal code**  
3415914595

**Approval date**  
2021-02-27, 1399/12/09

**Ethics committee reference number**  
IR.QUMS.REC.1399.512

## Health conditions studied

### 1

#### Description of health condition studied

Diarrhea

#### ICD-10 code

R19.7

#### ICD-10 code description

Diarrhea, unspecified

## Primary outcomes

### 1

#### Description

Diarrhea recovery time

#### Timepoint

Based on the length of hospital stay

#### Method of measurement

Day-Questionnaire

## Secondary outcomes

### 1

#### Description

Number of diarrhea

#### Timepoint

Duration of hospitalization

#### Method of measurement

Clinical examinations

### 2

#### Description

Synbiotic complication in children

#### Timepoint

Duration of hospitalization

#### Method of measurement

Clinical examinations

### 3

#### Description

Zinc complication in children

#### Timepoint

Duration of hospitalization  
**Method of measurement**  
Clinical examinations

## Intervention groups

### 1

#### Description

Control group:Synbiotic, Daily sachet pack containing probiotics and probiotic Kidi Lact(Kidi Lact of Tehran Bio Fermentation Company, which contains 7 probiotics)

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Zinc gluconate syrup in the amount of 5 mg every six hours(Zinc gluconate syrup of Amin Isfahan Pharmaceutical Company, which contains 5 mg of zinc element every 5 cc)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Quds Hospital

##### Full name of responsible person

Banafshe Samadpour

##### Street address

Valiasr Square, Shahid Beheshti St, Quds Hospital

##### City

Qazvin

##### Province

Qazvin

##### Postal code

3415914595

##### Phone

+98 28 3333 4807

##### Email

rad2180@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Research Assistant Quds Hospital

##### Street address

Valiasr Square, Shahid Beheshti St, Quds Hospital

##### City

Qazvin

##### Province

Qazvin

##### Postal code

3415914595

##### Phone

+98 28 3333 4807

##### Email

rad1280@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

##### Full name of responsible person

Banafshe Samadpour

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Pediatrics

##### Street address

Qods Hospital,Qods Square,Qazvin

##### City

Qazvin

##### Province

Qazvin

##### Postal code

3415914595

##### Phone

+98 28 3333 4807

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##### Email

Rad2180@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Banafshe Samadpour

##### Position

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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**Fax****Email**

Rad2180@yahoo.com

**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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

**Title and more details about the data/document**

All data can be shared after people are not identified

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

Data will be available for researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

Any kind of analysis on the delivered data is allowed. Send a message to the author's email to request access to data or documentation.

**From where data/document is obtainable**

banafshe samadpour - rad2180@yahoo.com

**What processes are involved for a request to access data/document**

After the publication of the article, the applicant is able to access the information by sending an email to the author and its duration is about one month

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

Qazvin University of Medical Sciences

**Full name of responsible person**

Banafshe Samadpour

**Position**

Resident

**Latest degree**

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