Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Research Assistant Quds Hospital

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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

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

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Person responsible for updating data

Contact
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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.comnv
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