

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effects of fructo-oligosaccharide and metronidazole on the control of infectious diarrhea in children

Protocol summary

Study aim

To determine the effects of fructo-oligosaccharide and metronidazole on the control of infectious diarrhea in children

Design

In this study, 120 infants with infectious diarrhea who were admitted to Amir al-Momenin Hospital of Zabol were selected. Participants were non-randomly allocated into two intervention groups of 60 participants, and each participant was assigned a code.

Settings and conduct

This double-blind trial was conducted in Amir al-Momenin Hospital of Zabol. The eligible patients were assigned to two intervention groups in a non-randomized manner. The first group received fructo-oligosaccharide, and the second group received metronidazole. Every four hours after the patients received the drugs for the first time, the symptoms of the patients were evaluated.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: Children suffering from infectious diarrhea and age between 60 and 180 months. Main non-inclusion criteria: Hepatic and renal failure.

Intervention groups

Intervention group 1 (metronidazole): 10 milligrams of metronidazole per kilogram body weight, three times daily until recovery; second intervention group (fructo-oligosaccharide): 10 milligrams of fructo-oligosaccharide per kilogram body weight three times daily until recovery

Main outcome variables

infectious diarrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170316033099N8**

Registration date: **2019-03-26, 1398/01/06**

Registration timing: **retrospective**

Last update: **2019-03-26, 1398/01/06**

Update count: **0**

Registration date

2019-03-26, 1398/01/06

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5680

Email address

roozgar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

2018-06-22, 1397/04/01

Scientific title

Comparison of the effects of fructo-oligosaccharide and metronidazole on the control of infectious diarrhea in children

Public title

The effect of probiotic and antibiotic drugs on diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children suffering from infectious diarrhea
Hospitalization in Amir al-Momenin Hospital of Zabol Age
between 60 and 180 months Informed consent of the
child's guardian

Exclusion criteria:

Hepatic failure Renal failure Patients with autoimmune
disease

Age

From **60 months** old to **180 months** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The participants and those who collected the data were
ignorant of the intervention received.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zabol University of Medical
Sciences

Street address

Shahid Rajaei Ave.

City

Zabol

Province

Sistan-va-Balouchestan

Postal code

9861615881

Approval date

2017-06-21, 1396/03/31

Ethics committee reference number

Zbmu.1.REC.1396.108

Health conditions studied**1****Description of health condition studied**

infectious diarrhea

ICD-10 code

A09.0

ICD-10 code description

Other and unspecified gastroenteritis and colitis of
infectious origin

Primary outcomes**1****Description**

infectious diarrhea

Timepoint

Every four hours from the first drug administration until
recovery

Method of measurement

observation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1 (metronidazole): metronidazole
made by Alborz Company, 10 milligrams per kilogram
body weight, three times daily until recovery

Category

Treatment - Drugs

2**Description**

Intervention group 2 (fructo-oligosaccharide): fructo-
oligosaccharide made by Zist-Takhmir Company, 10
milligram per kilogram body weight three times daily
until recovery

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir al-Momenin Hospital of Zabol

Full name of responsible person

Dr Mohadeseh Nikbakht

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Zahedan Road

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zabol University of Medical Sciences

Full name of responsible person

Dr Kaveh Tabrizian

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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

Zabol 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**

Zabol University of Medical Sciences

Full name of responsible person

Dr Mohadeseh Nikbakht

Position

Doctor of Medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

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Translator

Latest degree

Master

Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set

When the data will become available and for how long

When the paper extracted from the project is published and for six months

To whom data/document is available

readers of the paper

Under which criteria data/document could be used

Research purposes

From where data/document is obtainable

personal correspondence with the corresponding author

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

Email

Comments