Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Efficacy of oral probiotic in reducing of duration of diarrhea in children with acute colitis: a double blind randomized placebo controlled trial

Protocol summary

Study aim
Determining the effect of probiotics in comparison with placebo on the duration of diarrhea in patients with acute colitis

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 94 patients. Data analysis was performed using SPSS 22 statistical software.

Settings and conduct
This study conducted in Abuzar Hospital in Ahvaz. It is also a double-blind study. Probiotic powder and placebo are similar in appearance, taste and smell. Probiotic and placebo are quite similar. Were placed in packages sterile and assigned unit codes to each package. The patient delivering the drug to the patient and filling out the questionnaires were unaware of the type of drug in the package.

Participants/Inclusion and exclusion criteria
inclusion criteria: Patients admitted to the hospital for 3 months to 14 years due to acute infectious colitis are included in the study. The diagnosis of colitis is made by an emergency physician and patients who have fever and watery stools more than 3 times a day and less than 14 days have passed since the onset of the disease and with dysentery or the presence of more than 5 WBCs and any number of RBCs in the stool test. It is considered as colitis. Exclusion criteria: immunodeficiency, severe abdominal distension, severe infection or sepsis, or a history of gastrointestinal surgery or use of antibiotics or probiotics in the last two weeks, and patients who have been hospitalized due to oral intolerance or lack of response to treatment. The need for antibiotics other than azithromycin will be excluded.

Intervention groups
94 patients were enrolled in the study. Patients were randomly divided into two groups of intervention and control. Received a probiotic capsule brand under the brand name yomogi 250.

Main outcome variables
Duration of diarrhea, Vesikari score,duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161026030525N2**
Registration date: **2020-09-13, 1399/06/23**
Registration timing: **retrospective**

Last update: **2020-09-13, 1399/06/23**
Update count: **0**

Registration date
2020-09-13, 1399/06/23

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3444 3055

Email address
alizadeh.m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-07-05, 1395/04/15

Expected recruitment end date
2018-09-22, 1397/06/31

Actual recruitment start date
2016-08-22, 1395/06/01

Actual recruitment end date
2019-08-22, 1398/05/31

Trial completion date
2019-08-27, 1398/06/05

Scientific title
Efficacy of oral probiotic in reducing of duration of diarrhea in children with acute colitis: a double blind randomized placebo controlled trial

Public title
Efficacy of oral probiotic in reducing of duration of diarrhea in children with acute colitis: a double blind randomized placebo controlled trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria:Patients 3 months to 14 years of age admitted to the hospital due to acute infectious colitis. Patients with fever and watery stools more than 3 times a day and less than 14 days after the onset of the disease Dysentery or the presence of more than 5 WBCs and any number of RBCs in the stool test

Exclusion criteria:
Immunodeficiency Severe abdominal distension Severe infection or sepsis History of gastrointestinal surgery Use of antibiotics or probiotics in the last two weeks Patients who have been hospitalized due to oral intolerance or lack of response to treatment The need for antibiotics other than azithromycin.

Age
From **3 months** old to **14 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **94**
Actual sample size reached: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
Assignment of patients to each intervention and control groups will be done using winpepi software (random block method) and using six blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
Probiotic powder and placebo are similar in appearance, taste and smell. Probiotics and placebo, which are completely similar, were placed in packages in a sterile method and assigned a single code to each package. The patient and the questionnaire filler were unaware of the type of drug in the package.

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 Blvd. Ahvaz Jundishapur University of Medical Sciences - School of Medicine

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2016-04-23, 1395/02/04

Ethics committee reference number
IR.AJUMS.REC.1395.54

Health conditions studied

1

Description of health condition studied
Acute colitis

ICD-10 code
A09.0

ICD-10 code description
Other and unspecified gastroenteritis and colitis of infectious origin

Primary outcomes

1

Description
Duration of diarrhea

Timepoint
Before the intervention. The first day. The third day. The fifth day.

Method of measurement
Day

Secondary outcomes

1

Description
Frequency of diarrhea

Timepoint
Before the intervention. The first day. The third day. The fifth day.

Method of measurement
Number of times of diarrhea per day

2

Description
Duration of vomiting
Timepoint
Before the intervention. The first day. The third day. The fifth day.
Method of measurement
Number of days the patient vomits

3

Description
Frequent vomiting
Timepoint
Before the intervention. The first day. The third day. The fifth day.
Method of measurement
Number of times of vomiting per day

4

Description
Body temperature
Timepoint
Before the intervention. The first day. The third day. The fifth day.
Method of measurement
Maximum temperature every 24 hours

5

Description
Duration of hospitalization
Timepoint
End of hospitalization
Method of measurement
Number of days the patient is hospitalized

Intervention groups

1

Description
Intervention group: Supportive measures including intravenous or oral fluid therapy (ORS solution), antibiotic therapy (azithromycin suspension 12 mg per kg on the first day and then 6 mg per kg daily and the duration of treatment is 5 days). And zinc (zinc sulfate syrup for children under 6 months of age 10 mg daily and over 6 months of age 20 mg daily) in addition to the above treatments bulardi saccharomycesides in the form of probiotic capsules under the brand name yomogi 250. Children over 3 months receive a 250 mg capsule every 12 hours for up to 5 days (15) and in case of vomiting, the drug will be returned to the patient 15 minutes later.
Category
Treatment - Drugs

2

Description
Control group: The control group includes supportive measures including intravenous or oral fluid therapy (ORS solution), antibiotic therapy (azithromycin suspension 12 mg per kg on the first day and then 6 mg per kg daily and the duration of treatment is 5 days). And zinc (zinc sulfate syrup for children under 6 months of age 10 mg daily and over 6 months of age 20 mg daily)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Abuzar Hospital
Full name of responsible person
Mitra Ahmadi
Street address
Zeytonkarmandi, Blvd. Pasdaran, Tohid St.
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ahmadi-mi@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences of Medical Sciences
Full name of responsible person
Mohamad Badavi
Street address
Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences
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1579461357
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info@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences 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
Mitra Ahmadi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mitra Ahmadi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Masoomeh Alizadeh

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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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
Undecided - It is not yet known if there will be 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
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