Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Gastro-fix powder efficacy in pediatric acute gastroenteritis

Protocol summary

Study aim
evaluation of Gastro-fix powder efficacy in children with acute gastroenteritis
Design
This study is a double-blind controlled clinical trial.
Settings and conduct
In this study, patients who were diagnosed with acute gastroenteritis were admitted to Hazrat Masoumeh Salamullah Alaiha Hospital in Qom and were randomly divided into two groups receiving Gastrofix or placebo. Both groups will receive standard treatments.
Participants/Inclusion and exclusion criteria
Conditions for entering the study: formula feed children with acute gastroenteritis aged 6-24 months. Conditions for not entering the study: children with bloody diarrhea, malnutrition, severe dehydration and patients with underlying diseases.
Intervention groups
160 patients with acute gastroenteritis will be randomized into two groups and receive one of the following interventions: 80 patients will receive Gastro-fix (9 g/kg daily, in three divided doses) and 80 other patients in the control group will receive regular formula as a placebo (9 g/kg daily, in three divided doses). All patients will receive standard treatments and usual care.
Main outcome variables
1. days of hospitalization 2. times of diarrhea per day

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240508061709N1**
Registration date: **2024-05-12, 1403/02/23**
Registration timing: **prospective**

Last update: **2024-05-12, 1403/02/23**
Update count: **0**
Registration date
2024-05-12, 1403/02/23

Registrant information
Name
Fahime Aalishavandi
Name of organization / entity
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Iran (Islamic Republic of)
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+98 25 3296 0952
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-05-21, 1403/03/01
Expected recruitment end date
2024-08-22, 1403/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Gastro-fix powder efficacy in pediatric acute gastroenteritis

Public title
Gastro-fix powder efficacy in pediatric acute gastroenteritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
formula feed children with acute gastroenteritis aged 6 to 24 months
Exclusion criteria:
dysentery chronic diarrhea severe dehydration

malnutrition underlying diseases (such as inflammatory bowel disease; necrotizing enterocolitis; immune deficiency, etc.) Lack of parental consent

Age
From **6 months** old to **2 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to two groups A (standard treatment + Gastro-Fix powder) or B (standard treatment + placebo powder) based on the pattern determined in the R software blockrand package. Random allocation will be done in decimal blocks to obtain groups of similar size. The sequence will be hidden until the patients are determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Special codes are assigned to patients and provided to therapists. Neither the patient nor the therapist knows whether the oral medicine that is given to the patient in addition to the standard treatment is Gastrofix powder or a placebo. Both drugs are made in powder form by Fasca Co.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qom University of Medical Sciences

Street address
Qom, Iran

City
Qom

Province
Ghoum

Postal code
3716154433

Approval date
2024-03-16, 1402/12/26

Ethics committee reference number
IR.MUQ.REC.1403.029

Health conditions studied

1

Description of health condition studied
Gastroenteritis

ICD-10 code
A08.4

ICD-10 code description
Viral intestinal infection, unspecified

Primary outcomes

1

Description
length of hospitalization

Timepoint
after intervention

Method of measurement
Number of hospitalization days

2

Description
Frequency of diarrhea

Timepoint
after intervention

Method of measurement
Number

Secondary outcomes

1

Description
percentage of dehydration

Timepoint
Before and after the intervention

Method of measurement
The percentage of dehydration according to the dehydration scale of the World Health Organization

2

Description
stool consistency

Timepoint
before and after intervention

Method of measurement
stool consistency score

Intervention groups

1

Description
Intervention group: patients will receive Gastro-fix, 9 g/kg in three divided doses per day.

Category
Treatment - Other

2

Description
Control group: patients will receive regular formula 9 g/kg in three divided doses per day.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Masoumeh Hospital
Full name of responsible person
Fahime Alishavandi
Street address
Imam Street, Shahid Zainuddin Square, Hazrat Masoumeh Hospital
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3713649373
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f.aalishavandi24@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr. Rahim Ali
Street address
Hazrat Masoumeh Hospital, Zainuddin Square, Qom
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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Fahime Aliahavandi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
The access period starts from September 2025.

To whom data/document is available
It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
A letter to the Vice-Chancellor of Medical Sciences Research, Qom

From where data/document is obtainable
Fahime Alishavandi 09173071474

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

Comments