

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Gastro-fix powder efficacy in pediatric acute gastroenteritis

Protocol summary

2024-05-12, 1403/02/23

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

Registrant information

Name

Fahime Aalishavandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3296 0952

Email address

f.aalishavandi24@gmail.com

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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Province

Ghous

Postal code

3713649373

Phone

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Email

f.aalishavandi24@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Dr. Rahim Ali

Street address

Hazrat Masoumeh Hospital, Zainuddin Square, Qom

City

Qom

Province

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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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Fahime Alishavandi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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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