

# 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

**City**

Qom

**Province**

Ghous

**Postal code**

3713649373

**Phone**

+98 25 3162 5224

**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**

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**Postal code**

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F.aalishavandi24@gmail.com

**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

#### Contact

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Ghous University of Medical Sciences

**Full name of responsible person**

Fahime Alishavandi

**Position**

Resident

**Latest degree**

Medical doctor

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## Person responsible for updating data

### Contact

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Fahime Alishavandi

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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**