# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## A clinical trial to compare the effectiveness of Gasro-Fix and placebo (lactose free dried milk) on duration of diarrhea among children with acute gastroenteritis

## Protocol summary


**Summary**

(1) Objective: The aim of this study is to investigate the effectiveness of Gasro-Fix on duration of hospitalization among children with acute gastroenteritis. (2) Design: This study is a double blind randomized controlled trial (3) Setting and conduct: This study will be done at Karaj Shahid Bahonar educational and Therapeutic Center. Eligible subjects will randomly receive one of the following treatments; Gasro-Fix and placebo. (4) major eligibility criteria: This clinical trial will be carried out on 150 patients of both sex with acute gastroenteritis and being at the age of 6-60 months. (5) Intervention: 150 patients with acute gastroenteritis will be randomly assigned into two groups and will receive one of the following two interventions; 75 patients will receive Gasro-Fix (9g/kg, daily, in two to four divided doses per day) and 75 patients in control group will receive lactose-free formula as placebo (9g/kg, daily, in two to four divided doses per day). All patients will receive regular standard treatment and routine care throughout the study. (6) Main outcome measures: the primary outcome variable in the study is the length of hospitalization. The secondary outcome measures include the following: body weight, severity of diarrhea will be defined by the stool consistency score and frequency of diarrhea in 24 hours, the state of dehydration, using the World Health Organization's dehydration scale.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017091536195N1**
Registration date: **2017-10-12, 1396/07/20**
Registration timing: **prospective**

Last update:

Update count: **0**

**Registration date**

2017-10-12, 1396/07/20

**Registrant information**


**Name**

Kumars Purrostami

**Name of organization / entity**

Alborz University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 26 3433 6009

**Email address**

kumarspurrostami@abzums.ac.ir


**Recruitment status**

**Recruitment complete**


**Funding source**

Alborz University of Medical Sciences


**Expected recruitment start date**

2017-11-22, 1396/09/01

**Expected recruitment end date**

2018-03-21, 1397/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A clinical trial to compare the effectiveness of Gasro-Fix and placebo (lactose free dried milk) on duration of diarrhea among children with acute gastroenteritis

**Public title**

Effect of Gasro-Fix on children acute diarrhea

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: child patients aged 6-60 months; diarrhea defined as the passage of three or more loose or liquid stools in 24 hours; diarrhea lasting at least 24 hours; and not exceeding two weeks from presentation of the disease; diarrhea with or without fever, vomiting, mucus in stool; Body weight more than 8 kg. Exclusion criteria: acute diarrhea that contains blood; chronic diarrhea; severe dehydration; inflammatory bowel disease; necrotizing enterocolitis; immune deficiency; chronic disease and malnutrition.

**Age**

From **6 months** old to **5 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

Block randomization

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

**Street address**

School of Medicine, Alborz University of Medical Sciences, Baghestan Boulevard, Karaj, Iran.

**City**

Karaj

**Postal code**

**Approval date**

2017-07-22, 1396/04/31

**Ethics committee reference number**

Abzums.Rec. 1396.52

## Health conditions studied

### 1

**Description of health condition studied**

gastroenteritis

**ICD-10 code**

A08.4

**ICD-10 code description**

Viral intestinal infection, unspecified

### 2

**Description of health condition studied**

gastroenteritis

**ICD-10 code**

A08.3

**ICD-10 code description**

Other viral enteritis

## Primary outcomes

### 1

**Description**

length of hospitalization

**Timepoint**

after intervention

**Method of measurement**

Number of hospitalization days

## Secondary outcomes

### 1

**Description**

body weight

**Timepoint**

befor and after intervention

**Method of measurement**

kg

### 2

**Description**

severity of diarrhea

**Timepoint**

befor and after intervention

**Method of measurement**

stool consistency score and frequency of diarrhea in 24 hours

### 3

**Description**

state of dehydration

**Timepoint**

befor and after intervention

**Method of measurement**

the state of dehydration, using the World Health Organization's dehydration scale

## Intervention groups

**1**

**Description**
Intervention group: patients will receive Gasro-Fix, 9 g/kg in two to four divided doses per day.
**Category**
Treatment - Other

**2**

**Description**
Control group: patients will receive lactose-free formula 9 g/kg in two to four divided doses per day
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Bahonar Hospital
**Full name of responsible person**
Kumars Purrostami
**Street address**
Shora Blvd, Azimieh, Karaj, Alborz Province
**City**
Karaj

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice Chancellor for research of Alborz University of Medical Sciences
**Full name of responsible person**
Dr Mostfa Qorbani
**Street address**
Vice chancellor for research, Alborz University of Medical Sciences, Baghestan Boulevard, Karaj, Iran.
**City**
Karaj
**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 of Alborz University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Alborz University of Medical Sciences
**Full name of responsible person**
kumars Purrostami
**Position**
Medical Specialist
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*