

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

before and after intervention

#### **Method of measurement**

kg

### 2

#### **Description**

severity of diarrhea

#### **Timepoint**

before and after intervention

#### **Method of measurement**

stool consistency score and frequency of diarrhea in 24 hours

### 3

#### **Description**

state of dehydration

#### **Timepoint**

before 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

#### Street address

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

#### City

Karaj

#### Postal code

#### Phone

+98 26 3433 6009

#### Fax

#### Email

kumarspurrostami@abzums.ac.ir

#### Web page address

## Person responsible for scientific 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

#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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#### Position

Medical specialist

#### Other areas of specialty/work

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**Phone**

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**Fax**

**Email**

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**Web page address**

**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*