

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

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

Street address

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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

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Person responsible for updating data

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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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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