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
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Person responsible for updating data

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Medical specialist
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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