

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The Effect of lactose-free formula on acute watery diarrhea in infants consuming formula

Protocol summary

Summary

This study is a clinical trial on 60 formula-fed infants aged 2 months to 5 years hospitalized with acute watery diarrhea in pediatric ward of Shahid Beheshti hospital in 2014. Patients with bloody diarrhea, malnutrition and systemic diseases are excluded from the study. Patients randomly assign into two groups. Experimental group receive lactose-free formula and the control group will receive standard formula. In two groups, treatment protocols for watery acute diarrhea shall be conducted. Duration and frequency of diarrhea within the past 24 hours is recorded daily by asking mothers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051611145N7**
Registration date: **2014-05-21, 1393/02/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-21, 1393/02/31

Registrant information

Name

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

sharif_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-05-10, 1393/02/20

Expected recruitment end date

2014-11-11, 1393/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of lactose-free formula on acute watery diarrhea in infants consuming formula

Public title

The Effect of lactose-free formula on acute watery diarrhea in infants consuming formula

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Formula-fed infants hospitalized with acute watery diarrhea in pediatric ward of Shahid Beheshti hospital; Aged 6 months to 2 years. Exclusion criteria: Bloody diarrhea; Malnutrition; Systemic diseases.

Age

From **6 months** old to **2 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Sciences
Street address
5th Km of Ghotbe Ravandi Bulv.
City
Kashan
Postal code
Approval date
2014-05-07, 1393/02/17
Ethics committee reference number
29/5/1/637/پ

Health conditions studied

1

Description of health condition studied
Acute Watery Diarrhea
ICD-10 code
A09.9
ICD-10 code description
Gastroenteritis and colitis of unspecified origin

Primary outcomes

1

Description
Stop Diarrhea
Timepoint
Daily
Method of measurement
Study of records & asking from mother

2

Description
Frequency of Diarrhea
Timepoint
Daily
Method of measurement
Study of records & asking from mother

3

Description
Duration of diarrhea
Timepoint
Daily
Method of measurement
Study of records & asking from mother

Secondary outcomes

1

Description
Admission period
Timepoint
At discharge
Method of measurement
Days recorded in dossier

Intervention groups

1

Description
Intervention: lactose-free formula
Category
Treatment - Drugs

2

Description
Control group: standard formula
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital
Full name of responsible person
Dr.Mohammad Reza Sharif
Street address
5th Km of Ghotbe Ravandi Bulv.
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholam Ali Hamidi
Street address
5th Km of Ghotbe Ravandi Bulv.
City

Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Sharif
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Associate Professor, Pediatric Infectious Diseases
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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