

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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
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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