Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Lactose-Free vs Lactose-Containing Formula in Dietary Management of Acute Diarrhea in infants 3-24 months admitted in Golestan and Abuzar hospitals in Ahvaz

Protocol summary

Study aim
The effect of lactose-free milk powder on the improvement of acute diarrhea in infants

Design
A clinical trial with a control , parallel, not-blinded, randomized groups, will be performed on Infants 3 to 24 months who consume formula and will be hospitalized following acute diarrhea (less than 14 days). Patients are randomly divided into two groups of at least 52 people by quadruple blocking method.

Settings and conduct
This trial will be performed in Abuzar and Golestan hospitals in Ahvaz during the spring and summer of 2015. After the initial emergency procedures and fluid therapy performed for them, In the intervention group of infants, lactose-free milk powder and in the control group, ordinary milk powder (containing lactose) is used for oral feeding by the researcher.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Infants 3 to 24 months; Using formula; acute diarrhea (less than 14 days); hospitalized.
Exclusion criteria: Diarrhea more than one week from the start of treatment, infants with congenital disease, underlying systemic disease, severe malnutrition, severe vomiting, history of antibiotic use in the last two weeks, having bloody stools and history of therapeutic milk powder treatment

Intervention groups
Intervention group: Feeding infants with lactose-free formula Control group: feeding infants with regular formula (containing lactose)

Main outcome variables
Patients' information including the infant's weight at the time of referral, the number of diarrhea during the first three days and weight gain after two, three and seven days from the start of hospitalization are recorded.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201011048995N1**
Registration date: **2021-02-18, 1399/11/30**
Registration timing: **retrospective**

Last update: **2021-02-18, 1399/11/30**
Update count: **0**
Registration date
2021-02-18, 1399/11/30

Registrant information
Name
Ali Nejadian
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2015-05-15, 1394/02/25
Expected recruitment end date
2015-08-19, 1394/05/28
Actual recruitment start date
2015-05-15, 1394/02/25
Actual recruitment end date
2015-08-19, 1394/05/28
Trial completion date
2015-08-19, 1394/05/28

Scientific title
Comparison of Lactose-Free vs Lactose-Containing Formula in Dietary Management of Acute Diarrhea in infants 3-24 months admitted in Golestan and Abuzar hospitals in Ahvaz

Public title
The effect of Lactose-Free vs Lactose-Containing Formula in Dietary Management of Acute Diarrhea in infants 3-24 month

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Infants 3 to 24 months Feeding with formula Acute diarrhea (less than 14 days)

Exclusion criteria:
Diarrhea more than a week from the start of treatment Infants with congenital disease Having an underlying systemic disease Severe malnutrition Having severe vomiting History of antibiotic use in the last two weeks Having bloody stools History of therapeutic milk powder consumption

Age
From **3 months** old to **24 months** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**
Actual sample size reached: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
A participant list was made consisting of the patients' ID that were numbered based on the order of referral. After completion of the eligible participants list, included patients are randomly assigned to two groups of at least 52 members using a computer-generated random queue with blocks size of 4 and an allocation ratio of 1:1 (permuted block randomization method). In other words, each block of participants could be arranged in 6 different ways, including AABB, ABAB, ABBA, BAAB, BABA, BBAA (A: group 1, B: group 2) for the purpose of achieving the allocation ratio of 1:1. Using random number generator application, then, one of the possible arrangements is randomly assigned to each block. AABB, ABAB, ABBA, BAAB, BABA, BBAA 1 2 3 4 5 6 7 8 9 10 11 12 …. Participants number:

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahwaz University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences and Health Services, Golestan Highway, Ahvaz, Khuzestan Province.

City
Ahvaz

Province
Khouzestan

Postal code
15794 - 61357

Approval date
2015-09-19, 1394/06/28

Ethics committee reference number
IR.AJUMS.REC.1394.349

Health conditions studied

1

Description of health condition studied
Diarrhea in infants

ICD-10 code
P78.3

ICD-10 code description
Noninfective neonatal diarrhea

Primary outcomes

1

Description
Number of times diarrhea

Timepoint
Daily for the first three days and after a week

Method of measurement
Note the number of watery stools per day In the data collection form

2

Description
Weight

Timepoint
at the time of referral and after two, three and seven days from the start of hospitalization

Method of measurement
Scale

Secondary outcomes

1

Description
Weight
Timepoint
After 48 and 72 hours and a week later
Method of measurement
Scale

2

Description
Number of times diarrhea
Timepoint
During the first three days and after a week
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: All patients undergo standard treatment for diarrhea (intravenous and oral fluid therapy and zinc sulfate syrup) and depending on the usual consumption of infants, we will first give the lactose-free quota to mothers of infants in the intervention group. And while teaching them how to prepare it properly, we ask them to use lactose-free milk powder for a week.
Category
Diagnosis

2

Description
Control group: All patients undergo standard treatment for diarrhea (intravenous and oral fluid therapy and zinc sulfate syrup) and mothers of infants in the control group are also explained the correct way to prepare powdered milk (normal, lactose).
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Ali Nejadian
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Farvardin Boulevard (Shahid Shabibi) -Golestan - Ahvaz -Khuzestan
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2

Recruitment center
Name of recruitment center
Abuzar Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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shahossayni@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private

Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Shideh Assar
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available