Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of lactose restricted diet in the treatment of pediatric acute diarrhea treated with zinc

Protocol summary

Summary

This study is a blinded clinical trial.This study will be conducted on 90 children with acute watery diarrhea, which in 1395 referred to gastrointestinal clinic Amirkola Children's Hospital(Babol University of Medical Sciences). Children randomly (simple) are divided into two groups: The first group,45 patients receive syrup zinc sulfat(daily20mg) and lactose restricted diet (continued breastfeeding along with the elimination of lactose from the diet, especially the elimination of milk and the use of lactose-free supplement). The second group,45 patients received syrup zinc sulfat(daily20mg) and breast milk with normal diet. Inclusion criteria:children 6 months to 2 years with acute watery diarrhea(i.e.3 or more stools per day for less than 72 h). Exclusion criteria:children under 6 months and more than two years, blood in the stool (dysentery infectious and non-infectious), more than 3 days have passed since the onset of diarrhea, recent use of antibiotics, organic diseases (heart, kidney, etc. .) is known, severe malnutrition (weight for age <60% and/or weight for height <70%), Where diarrhea is causing complications such as seizures and ileus.All patients treated for 2 weeks and will be followed up and the number of defication, Presence or absence of Watery stools and Time to recover watery stools this information will be asked by phon from child mother and Will be recorded in a questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031326973N1**
Registration date: **2016-03-13, 1394/12/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

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Sanaz Mehrabani
Name of organization / entity
Babol University of Medical sciences
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Recruitment status

Recruitment complete

Funding source

vice chancellor for research- Babol University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lactose restricted diet in the treatment of pediatric acute diarrhea treated with zinc

Public title

Effect of lactose restricted diet in the treatment of pediatric acute diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:children 6 months to 2 years with acute watery diarrhea(i.e.3 or more stools per day for less than 72 h) Exclusion criteria:children under 6 months and more than two years, blood in the stool (dysentery infectious and non-infectious), more than 3 days have passed since the onset of diarrhea, recent use of antibiotics, organic diseases (heart, kidney, etc. .) is known, severe malnutrition (weight for age <60% and/or weight for height <70%), Where diarrhea is causing complications such as seizures and ileus.

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: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Babol University of Medical Sciences

Street address

Babol-Ganj afrooz Street-Babol University of Medical Sciences,Department of TResearch and Technology Babol

City

Babol

Postal code

4717641367

Approval date

2016-02-08, 1394/11/19

Ethics committee reference number

mubabol.HRI.REC.1394.6

Health conditions studied

1

Description of health condition studied

acute diarrhea

ICD-10 code

A00,A01,A0

ICD-10 code description

Intestinal infectious diseases

Primary outcomes

1

Description

The number of defication per day

Timepoint

Before the intervention, the duration of intervention for 14 days, at the end of intervention

Method of measurement

Improve the diarrhea is defined as the number of bowel movements fewer than three times in 24 hours

Secondary outcomes

1

Description

There are possible side effects of the drug and lactose-free supplement

Timepoint

During the study period and at the end of the study

Method of measurement

according to patiants

Intervention groups

1

Description

Intervention Group: zinc sulfat syrup(daily 20mg) and lactose restricted diet (continued breastfeeding along with the elimination of lactose from the diet, especially the elimination of milk and the use of lactose-free supplement). Zinc sulfate syrup 5 mg / 5ml, 20mg daily for 14 days and GASTRO_FIX(Product by behdashtkar company) as lactos free supplement for children 6_12 month: 7 Cup flat head dissolved in the 210ml boild water(5 times in 24 hours).For children one year and more: 8 Cup flat head dissolved in the 240ml boild water(5 times in 24 hours). GASTRO_FIX Used for 14 days. control Group: zinc sulfat syrup(daily 20mg) and breast milk with normal diet. Zinc sulfate syrup 5 mg / 5ml, 20mg daily for 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Hospital Decedent Shafi'zadeh Amirkola

Full name of responsible person

Sanaz Mehrabani (Pediatric gastroenterologist)
Street address
Babol-Amirkola-Children's Hospital Decedent Shafi'zadeh Amirkola
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research- Babol University of Medical Sciences
Full name of responsible person
Hadi Parsian(Research Assistant)
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Babol
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- Babol 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

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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