

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 (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). The second group, 45 patients received syrup zinc sulfat (daily 20mg) 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 defecation, Presence or absence of Watery stools and Time to recover watery stools this information will be asked by phone 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

Name

Sanaz Mehrabani

Name of organization / entity

Babol University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

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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 defecation 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 patients

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 boiled water(5 times in 24 hours).For children one year and more: 8 Cup flat head dissolved in the 240ml boiled 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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Web page address

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)

Street address

Babol- Ganj Afrooze Street- University of Medical
Sciences- Vice Chancellor for research

City

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

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sanaz Mehrabani

Position

Pediatric gastroenterologist/Assistant Professor Babol
University of Medical Sciences

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Reza Tarahomi

Position

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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