

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Therapeutic effects of oral zinc supplementation in acute watery diarrhea of children with moderate dehydration: a double blind randomized clinical trial

Protocol summary

Summary

Objective: to assess the therapeutic effects of oral zinc supplementation in acute watery diarrhea of children with moderate dehydration. This double blind randomized clinical trial was done in Urmia. Methods: all 9 months to 5 years old children who were admitted with acute watery diarrhea and moderate dehydration at Children Ward of Motahari Hospital, Urmia, Iran in 2008 were recruited. After applying inclusion and exclusion criteria, patients were randomly allocated in two groups; receiving zinc sulfate (zinc syrup 1 mg/kg/day divided in two doses)+ oral rehydration solution (ORS) or placebo + ORS. A detailed questionnaire was filled daily for each patient by trained pediatrics residents containing required demographic characteristics, nutrition and hydration status and disease progression. Two groups compared for study outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201241580N2**

Registration date: **2012-02-17, 1390/11/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-17, 1390/11/28

Registrant information

Name

Shahsanam Gheibi

Name of organization / entity

Maternal and Childhood Obesity research Center,
Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Challencor for research, Urmia University of Medical Sciences

Expected recruitment start date

2008-04-02, 1387/01/14

Expected recruitment end date

2009-03-19, 1387/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of oral zinc supplementation in acute watery diarrhea of children with moderate dehydration: a double blind randomized clinical trial

Public title

Therapeutic effects of oral zinc supplementation in acute watery diarrhea of children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all 9 months to 5 years old children who were admitted with acute watery diarrhea and moderate dehydration at Children Ward of Motahari Hospital, Urmia, Iran in 2008 were recruited. The exclusion criteria were diagnosed chronic disease (Cystic

fibrosis, inflammatory bowel diseases, malabsorption); severe malnutrition (weight curve's was under percentage 3% for age); dysentery and bloody diarrhea confirmed with existence of red blood cell (RBC) or white blood cell (WBC) in stool examination (S/E); recent consumption of antibiotics; severe dehydration or persistent vomiting; recent consumption of zinc supplements (last month) and drug intolerance.

Age

From **1 year** old to **5 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **320**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Urmia University of Medical Sciences

Street address

Resalat Ave

City

Urmia

Postal code**Approval date**

2008-12-02, 1387/09/12

Ethics committee reference number

39

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**

Stool consistency

Timepoint

daily

Method of measurement

Mothers report

Secondary outcomes**1****Description**

admission period

Timepoint

days of admission

Method of measurement

days recorded in dossier

Intervention groups**1****Description**

Zinc Sulfate Syrup, 1mg/kg/day/BID

Category

Treatment - Drugs

2**Description**

Placebo with similar taste, color and smell was applied with similar option (1 ml/kg/day) for control group.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Motahari Hospital

Full name of responsible person

Shahryar Kamali, pediatrics Resident

Street address**City**

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chencellor for Research, Urmia Univesity of Medical Sciences

Full name of responsible person

Morteza Motazaker

Street address

Resalat Ave

City

Urmia

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chencellor for Research, Urmia Univesity 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

Urmia University of medical Sciences

Full name of responsible person

Shahsanam Gheibi

Position

Pediatrics Gastroenterologist, Associate Professor

Other areas of specialty/work

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Other areas of specialty/work

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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