

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 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)

##### Phone

+98 44 3222 6969

##### Email address

drgheibi@umsu.ac.ir

##### 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

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**Web page address**

## Person responsible for scientific inquiries

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## Person responsible for updating data

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Urmia University of Medical Sciences

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**Position**

Pediatrics Gastroentrolgist, Associate Professor

**Other areas of specialty/work****Street address**

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**City**

Urmia

**Postal code****Phone****Fax****Email****Web page address**

## 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*