

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Impact of Zinc Supplementation on Diarrhea Duration and Severity in Hospitalized Children in Ardabil

#### Protocol summary

##### Summary

Recent studies reported that zinc significantly reduces duration and severity of acute diarrhea in children. Zinc deficiency is prevalent in children in developing countries. Supplemental zinc provides therapeutic benefits in diarrhea. Our aim was to evaluate the effect of zinc supplementation on diarrhea duration and severity among children aged <5 y. This study was a double-blind, randomized, placebo controlled trial. Children (228 subjects) who hospitalized with an acute diarrhea were randomly assigned in two groups A and B to receive 20 mg Zn sulfate or placebo (glucose 5%), Children who hospitalized with acute diarrhea included in study and whom had perior of hospitalization and severe illness in two last months excluded. Then duration and severity of diarrhea were assessed during the study

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201103065989N1**

Registration date: **2011-05-30, 1390/03/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-05-30, 1390/03/09

##### Registrant information

###### Name

Afrouz Mardi

###### Name of organization / entity

Ardabil University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3327 1159

###### Email address

a.mardi@arums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Official- Research Assistant of Ardabil University of Medical Sciences

###### Expected recruitment start date

2005-03-21, 1384/01/01

###### Expected recruitment end date

2006-03-20, 1384/12/29

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Impact of Zinc Supplementation on Diarrhea Duration and Severity in Hospitalized Children in Ardabil

###### Public title

Zinc Supplementation and Diarrhea in Children

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion: Children who hospitalized with acute diarrhea  
Exclusion: Children who had perior of hospitalization and severe illness in two last months.

###### Age

To **5 years** old

###### Gender

Both

###### Phase

N/A

###### Groups that have been masked

*No information*

## Sample size

Target sample size: **228**

## Randomization (investigator's opinion)

Randomized

## Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

There aren't the other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ardabil University of Medical Sciences

##### Street address

Daneshgah street- Ardabil

##### City

Ardabil

##### Postal code

#### Approval date

2005-10-06, 1384/07/14

#### Ethics committee reference number

82165

## Health conditions studied

### 1

#### Description of health condition studied

Diarrhea

#### ICD-10 code

A09

#### ICD-10 code description

Diarrhoea and gastroenteritis of presumed infectious origin

## Primary outcomes

### 1

#### Description

Duration of diarrhea

#### Timepoint

Number of hospitalization days were used as duration time.

#### Method of measurement

Number of hospitalized days

### 2

#### Description

Severity of diarrhea

#### Timepoint

Daily during the hospitalization time

#### Method of measurement

Number of defecation in day

## Secondary outcomes

### 1

#### Description

There weren't secondary outcome measure

#### Timepoint

There weren't secondary outcome measure

#### Method of measurement

There weren't secondary outcome measure

## Intervention groups

### 1

#### Description

Intervention group received 20 mg zinc sulfate in dextrose 5% daily plus their routine drugs during the hospitalization time.

#### Category

Treatment - Drugs

### 2

#### Description

Control group received 5 cc dextrose 5% daily plus their routine drugs during the hospitalization time.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ali Asghar Hospital

##### Full name of responsible person

Mrs Panahi Farahnaz

##### Street address

Varzesh Square -Ardabil

##### City

Ardabil

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ardabil University of Medical Sciences

##### Full name of responsible person

Dr Peeri Hadi

**Street address**

Daneshgah Street- Medical School- Ardabil University  
of Medical Sciences

**City**

Ardabil

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Afrouz Mardi

**Position**

Master Science/ Lecturer

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

Health School

**City**

Ardabil

**Postal code**

5618953141

**Phone**

+98 45 1552 0477

**Fax**

+98 45 1551 3775

**Email**

a.mardi@arums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Afrouz Mardi

**Position**

master science / lecturer

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

Health School

**City**

Ardabil

**Postal code**

5618953141

**Phone**

+98 45 1552 0477

**Fax**

+98 45 1551 3775

**Email**

a.mardi@arums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Afrouz Mardi

**Position**

Master Science/ Lecturer

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

Health School- Ardabil University of Medical Sciences-  
Ardabil

**City**

Ardabil

**Postal code**

56189 53141

**Phone**

+98 45 1552 0477

**Fax**

+98 45 1551 3775

**Email**

a.mardi@arums.ac.ir

**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*