

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparing the effect of Zinc sulfate and Zinc gluconate on serum level of Zinc and improvement of acute diarrhea in children under 5 years

#### Protocol summary

##### Summary

This study is a clinical trial on 150 children aged 1-5 years. Patients admitted with complaints of acute watery diarrhea in Beheshti Hospital with the following characteristics are enrolled: Aged 1-5 years- Without dysentery that is confirmed by stool exam- Children with axillary temperature  $\geq 38^\circ$  are excluded from the study. Serum zinc level is measured by taking 5cc blood sampling on admission. Patients randomly assign into three groups. Experimental group1 receive Zinc sulfate1cc / kg of solution1% Razak Company and experimental group 2 receive Zinc gluconate1cc / kg of solution1% Alhavy Company daily.The control group will receive like ORS solution 1cc / kg /daily. In three groups, treatment protocols for watery acute diarrhea shall be conducted. Frequency and duration of diarrhea within the past 24 hours is recorded by asking mothers. The serum Zinc level in the end of diarrhea will be tested at discharge.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012123111145N3**

Registration date: **2013-03-10, 1391/12/20**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-03-10, 1391/12/20

##### Registrant information

##### Name

Mohammad Reza Sharif

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0026

##### Email address

sharif\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kashan University of Medical Sciences

##### Expected recruitment start date

2013-02-19, 1391/12/01

##### Expected recruitment end date

2014-02-20, 1392/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of Zinc sulfate and Zinc gluconate on serum level of Zinc and improvement of acute diarrhea in children under 5 years

##### Public title

Comparing the effect of Zinc sulfate and Zinc gluconate on serum level of Zinc and improvement of acute diarrhea in children under 5 years

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Children hospitalized with acute gastroenteritis in Shahid Beheshti hospital; Aged 1 - 5 years. Exclusion criteria: Dysentery confirmed by stool exam; Axillary temperature equal to or more than  $38^\circ$  C.

##### Age

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

##### Gender

Both

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: **150**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kashan University of Medical Sciences

##### Street address

5th Kilometer, Ghotbe Ravandi Bulv, Kashan

##### City

Kashan

##### Postal code

#### Approval date

2013-02-17, 1391/11/29

#### Ethics committee reference number

4227/1/5/29/پ

## 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

Duration of diarrhea

#### Timepoint

Daily

#### Method of measurement

Study of records & asking from mother

### 3

#### Description

Frequency of Diarrhea

#### Timepoint

Daily

#### Method of measurement

Study of records & asking from mother

### 4

#### Description

Admission period

#### Timepoint

at discharge

#### Method of measurement

Days recorded in dossier

### 5

#### Description

Serum zinc level

#### Timepoint

on admission - at discharge

#### Method of measurement

Blood test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Oral administration of Zinc sulfate 1cc / kg of solution 1% daily

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Oral administration of Zinc gluconate 1cc / kg of solution 1% daily

#### Category

Treatment - Drugs

### 3

#### Description

Control group: Oral administration of like ORS solution 1cc / kg /daily

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Beheshti Hospital

**Full name of responsible person**

Dr.Mohammad Reza Sharif

**Street address**

Beheshti Hospital, 5th Kilometer, Ghotbe Ravandi Bulv, Kashan

**City**

Kashan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr.Gholamali Hamidi

**Street address**

Kashan University of Medical Sciences, 5th Kilometer, Ghotbe Ravandi Bulv, Kashan

**City**

Kashan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kashan 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

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Reza Sharif

**Position**

Associate Professor, Pediatric Infectious Diseases Subspecialist

**Other areas of specialty/work**

**Street address**

Kashan University of Medical Sciences, 5th Kilometer, Ghotbe Ravandi Bulv, Kashan

**City**

Kashan

**Postal code**

8715985131

**Phone**

+98 36 1555 0026

**Fax**

+98 36 1555 8900

**Email**

mrsharifmd@yahoo.com

**Web page address**

www.drsharif.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Reza Sharif

**Position**

Associate Professor, Pediatric Infectious Diseases Subspecialist

**Other areas of specialty/work**

**Street address**

Kashan University of Medical Sciences, 5th Kilometer, Ghotbe Ravandi Bulv, Kashan

**City**

Kashan

**Postal code**

8715985131

**Phone**

+98 36 1555 0026

**Fax**

+98 36 1555 8900

**Email**

mrsharifmd@yahoo.com

**Web page address**

www.drsharif.ir

## 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*

