

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

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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° 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**

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Person responsible for updating data

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Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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Position

Associate Professor, Pediatric Infectious Diseases Subspecialist

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

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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

