

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The Effect Of Zinc Gloconate Supplementation in Children With Acute Diarrhea .

Protocol summary

Summary

According to recent studies on the effect of zinc on reducing diarrhea in developing and poor countries ,the aim of this study is to evaluate the effect of zinc in childrens with diarrhea based on their socioeconomic levels. About 70 children with diarrhea will participate in this study with ages between 6 months and 5 years. This survey is done in Emam Hossein Pediatric Hospital in Isfahan.The steps of this survey are as followed: 1. preparation of drug and placebo with same shape, size and color and blindly 2. fulfilling patients special forms including patient's age, duration of diarrhea and socioeconomic variables 3. consumption of drug 4. follow up in days 2, 5, 14 and 1 and 3 months after administration of drug 5. data entry and statistical analysis 6. unblinding cases and reporting outcomes
Inclusion Criteria: 1. ages between 6 months and 5 years 2.duration of diarrhea between 24 and 72 hours 3.lack of any underlying disorder (For example Reflux,Asthma,Heart Disease,Epilepsy,Convulsion,FTT,Developmental Delay,Diabetes,Metabolic Disorder,Cancer) 4. No recent Major surgery around three months ago , Minor Surgery around one month ago. 5.No recent consumption of antibiotics in recent two weeks 6. No recent consumption of zinc supplementation in recent 6 months
Exclusion Criteria: vomiting more than 2 times in 24h. If the patient has vomiting with zinc, they will treated. Decreasing diarrhea and decreasing respiratory infection are major incomes in this survey.

General information

Acronym

Zinc Gloconate

IRCT registration information

IRCT registration number: **IRCT2015123125780N1**

Registration date: **2016-11-17, 1395/08/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-17, 1395/08/27

Registrant information

Name

Naser Mostafavy

Name of organization / entity

Department of Pediatrics , School of Medical , Isfahan University of Medical Sciences, Hezar Jerib

Country

Iran (Islamic Republic of)

Phone

none

Email address

n_mostafavy@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University Of Medical Sciences

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2017-01-01, 1395/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Zinc Gloconate Supplementation in Children With Acute Diarrhea .

Public title

The Effect Of Zinc Gloconate Supplementation In Treatment Of Diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1.Children with ages between 6 months and five years. 2. Children with diarrhea duration more than 24 hours and less than 72 hours 3. lack of any underlying disorder (For example Reflux,Asthma,Heart Disease,Epilepsy,Convulsion,FTT,Developmental Delay,Diabetes,Metabolic Disorder,Cancer) 4. No recent Major surgery in three months ago , Minor Surgery in one month ago. 5. No recent consumption of antibiotics in recent two weeks 6. No recent consumption of zinc supplementation in recent six months . Exclusion Criteria: vomiting more than two times in 24hours

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University Of Medical Sciences

Street address

Hezar Jarib Street , Isfahan

City

Isfahan

Postal code

8174643446

Approval date

2014-12-22, 1393/10/01

Ethics committee reference number

none

Health conditions studied

1

Description of health condition studied

acute diarrhea

ICD-10 code

K93

ICD-10 code description

Diseases of the digestive system

Primary outcomes

1

Description

durationof diarrhea. frequency of diarrhea,respiratory infection

Timepoint

2,14 days.3,6 months

Method of measurement

ask from parents ,filling the form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Zinc sulfate, 10 mg tablet taken orally, once daily, for 14 days, in children under 6 months Control group: placebo, 10 mg tablet taken orally, once daily, for 14 days, in children under 6 months

Category

Treatment - Drugs

2

Description

Intervention group: Zinc sulfate, 20 mg tablet taken orally, once daily, for 14 days, in children older than 6 months Control group: placebo, 20 mg tablet taken orally, once daily, for 14 days, in children older than 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr.Mosafavy-Dr.Soleymani

Street address

Imam Hossein Hospital.Imam Khomeini Street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

Dr. Mostafavy

Street address

Hezar Jarib Street

City

Isfahan

Grant name

ندارم

Grant code / Reference number

None

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

Yes

Title of funding source

Isfahan 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

Isfahan University Of Medical Sciences

Full name of responsible person

Mrs.Vakili Zahra

Position

Responsible Of Scientific Unit

Other areas of specialty/work

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None

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Esfahan University Of Medical Sciences

Full name of responsible person

Dr.Mostafavy

Position

Professor Of Peditric Medicine Of Esfshan

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Emam Hossein Hospital

Full name of responsible person

Dr Mostafavy

Position

Professor Of Pediatric Esfahan

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