Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of oral zinc sulfate effect on the duration of treatment in children with acute gastroenteritis admitted in pediatrics ward

Protocol summary

Summary

Aim: to evaluate the effect of oral zinc sulfate syrup in children with acute gastroenteritis. Method: this study was performed as a randomized double blind trial. Overall 400 children admitted with acute gastroenteritis, who are 6-24 months breast fed infants with mild to moderate dehydration with at least 2 days of gastroenteritis whose parents fill the consent form. Patients was receiving complementary foods during last month and antibiotic during admission and patients with severe FTT were excluded from study. They were divided into two equal groups. The case group took oral zinc sulfate 22 mg daily and control group was given the placebo. Information was gathered with questionnaires and recorded precisely over 10 days. The outcome of this trial: assessment the improvement of symptoms and duration of disease in children under treatment with zinc sulfate in compression to placebo.

General information

Acronym

GE

IRCT registration information

IRCT registration number: **IRCT138902203900N1**
Registration date: **2010-08-30, 1389/06/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-08-30, 1389/06/08

Registrant information

Name

Zohre Torabi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 1727 4857

Email address

mohamad@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2007-04-10, 1386/01/21

Expected recruitment end date

2009-08-10, 1388/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of oral zinc sulfate effect on the duration of treatment in children with acute gastroenteritis admitted in pediatrics ward

Public title

Assessment of oral zinc sulfate effect on the duration of treatment in children with acute gastroenteritis(GE) admitted in pediatrics ward

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 6-24 months breast fed infants with mild to moderate dehydration with at least 2 days of gastroenteritis whose parents fill the consent form.
Exclusion criteria: receiving complementary foods during last month and antibiotic during admission, severe FTT.

Age

From **6 years** old to **2 years** old

Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **400**
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
Ethics Committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences
City
Zanjan
Postal code
4515613191
Approval date
2010-05-30, 1389/03/09
Ethics committee reference number
19/3-3/1001

Health conditions studied

1

Description of health condition studied
Gastroenteritis
ICD-10 code
A09
ICD-10 code description
Diarrhoea and gastroenteritis of presumed infectious origin

Primary outcomes

1

Description
Improvement of symptoms
Timepoint
daily
Method of measurement
clinical assessment

Secondary outcomes

1

Description
weight gain
Timepoint
daily
Method of measurement
weight measurment with seca instrument

Intervention groups

1

Description
Control group: 5cc of dextrose water 5% as placebo, once daily
Category
Placebo

2

Description
Case group: 5cc of zinc sulfate (22 mg) once daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mousavi Hospital
Full name of responsible person
Zohre Torabi
Street address
Gavasang road
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University Of Medical Sciencs
Full name of responsible person
Alireza Biglari
Street address
Zanjan University of Medical Sciences
City
Zanjan
Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan University Of Medical Sciencs

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

Zanjan University of Medical Sciences

Full name of responsible person

Zohre Torabi

Position

Assistant prof, specialist of pediatic

Other areas of specialty/work

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Gavasang road , Mousavi hospital

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4513956183

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Email

drztorabi@yahoo.com

Web page address

Person responsible for updating data

Contact

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