

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Sciences

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 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
Zanjan University of Medical Sciences

Full name of responsible person
Zohre Torabi

Position
Assistant prof, specialist of pediatric

Other areas of specialty/work

Street address

Gavasang road , Mousavi hospital

City

Zanjan

Postal code

4513956183

Phone

+98 24 1727 4857

Fax

+98 24 1413 1140

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