

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 comparison 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 measurement 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 pediatic

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

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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*