Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of zinc sulfate on prevention of diarrhea due to coamoxiclave in pediatric 6-60 MO

Protocol summary

Summary

The purpose of this study is to investigate the effect of zinc sulfate supplementation on prevention of diarrhea due to coamoxiclave.This study is randomized clinical trial. A Total of 120 children suffering from otitis media that have indication of using coamoxiclave were enrolled. Exclution criteria is severe malnutrition; using antibiotic in 2 recent week; chronic illness; systemic disease that need to hospitalized; severe dehydration; fluide intoleranc; using immunosuppressive drug; using drugs causing diarrhea or constipation; using zinc supplement in two recent month; Parent who do not cooperate. After interview and accept parent satisfaction،their children were enrolled in this study. We will prescribe zinc sulfate 2mg/kg/day and also coamoxiclave 80mg/kg/day for intervention group but controll group only recieve coamoxiclave at the same dosage. Using drugs continue for seven days in this study. The researcher investigate patient condition about the number of defication on third and seventh days. Then we will collect data in questionnaire . Primary outcome is to consider number of defication and the secondry outcomes are weight loss and hospitalization

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100119354N1**
Registration date: **2014-11-15, 1393/08/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-15, 1393/08/24

Registrant information

Name

Maryam AlSadat Yazdanparast

Name of organization / entity

Shahid Sadoughi University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 35 1828 5793

Email address

yazdanparastmaryam89@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Shahid Sadoghi University of Medical Science

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of zinc sulfate on prevention of diarrhea due to coamoxiclave in pediatric 6-60 MO

Public title

The effect of zinc sulfate on prevention of diarrhea

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of 6 to 60 mo with otitis media
Exclution criteria: Severe Malnutrition; Using antibiotic in 2 recent week; Chronic illness; systemic disease that need to hospitalized; Severe dehydration; fluide intolerance; Using immunosuppressive drugs; Using

drugs causing diarrhea or constipation; Using zinc supplement in two recent month; Parent who do not cooperate

Age
From **6 months** old to **6 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Sadoghi University of Medical Science

Street address
Bahonar sq, Yazd

City
Yazd

Postal code

Approval date
2014-03-18, 1392/12/27

Ethics committee reference number
257428 /1/17/ پ

Health conditions studied

1

Description of health condition studied
Non infective enteritis and colitis

ICD-10 code
k52

ICD-10 code description
Other noninfective gastroenteritis and colitis

Primary outcomes

1

Description
Number of defecation in day

Timepoint
Third and seventh day of treatment

Method of measurement
Asking from mothers of patients

Secondary outcomes

1

Description
Hospitalization

Timepoint
First day until seventh day of treatment

Method of measurement
Asking from mothers of patient

2

Description
Weight loss

Timepoint
Seventh day of treatment

Method of measurement
Weighting patient by resident

Intervention groups

1

Description
Intervention group: Zinc sulfate syrup (manufacture by Alhavi Co, Iran) 2mg/kg/day divided in two equal dosage and coamoxiclave syrup (manufacture by Abidi Co, Iran) 80mg/kg/day divided in tree equal dosage will prescribe whitin seven days

Category
Prevention

2

Description
Control group: Coamoxiclav (manufacture by Abidi Co, Iran) 80mg/kg divided in tree equal dosage will prescribe whitin seven days

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoghi Hospital

Full name of responsible person
Dr Maryam Al Sadat Yazdanparast

Street address
Shahid Sadoughi Hospital; Shahid Ghandi Avenue;

Atlasi Square; Yazd

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Shahid Sadoghi University of Medical Science

Full name of responsible person

Dr Fateme Ezodini

Street address

Vice Chancellor for Research Shahid Sadoghi University of Medical Science, Bahonar sq

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research Shahid Sadoghi University of Medical Science

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

Shahid Sadoghi Hospital

Full name of responsible person

Dr Mahmood Noori Shadkam

Position

Neonatologist

Other areas of specialty/work

Street address

Shahid Sadoghi Hospital, Shahid Ghandi Blvd, Yazd

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Email

Mahmood _7072005@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoghi Hospital

Full name of responsible person

Dr. Mehran Karimi

Position

Pediatrician

Other areas of specialty/work

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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