Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Zinc Sulfate on clinical symptoms of acute bronchiolitis in children less than 2 years old

Protocol summary

Summary

Introduction: Acute bronchiolitis may lead to hospitalization with some morbidity and mortality. Finding some agents to reduce severity of disease can improve morbidity and mortality. Objectives & (hypothesis OR questions): To evaluate the effect of zinc sulfate in improving the clinical manifestations of acute bronchiolitis in children younger than 2 years old. Materials & Methods: It was a double blind pilot trial on patients, age 2 months to 23 months at Ghaem and Dr. Sheikh hospitals in Mashhad from Jan 2008 to March 2009. Patients randomly divided into two groups: case group who took oral zinc sulfate 1% (1 CC per kg in infants below 1 year old and 10 CC (20 mg of elemental zinc) for children above 1 year old during hospitalization and controls who received placebo. Bottles of drugs were similar in shape and size. Inclusion criteria: Age 2 months to 23 months, first attack of wheezing. Exclusion criteria: Any history of previous wheezing attack(s), congenital heart disease, severe malnutrition, any history of taking zinc sulfate last month and pneumonia. Clinical manifestation including tachypnea, wheezing , cyanosis, intercostal and subcostal retractions and nasal flaring at admission, 24 , 48, and 72 hours after hospitalization were assessed. Recovery from acute bronchiolitis was defined as; complete disappearance of tachypnea, intercostal and subcostal retractions , wheezing and cyanosis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011065114N1**
Registration date: **2010-12-23, 1389/10/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-12-23, 1389/10/02

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Mashhad university of medical sciences

Expected recruitment start date

2008-01-10, 1386/10/20

Expected recruitment end date

2009-03-16, 1387/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Zinc Sulfate on clinical symptoms of acute bronchiolitis in children less than 2 years old

Public title

The role of zinc sulfate in acute bronchiolitis in patients aged 2 months to 23 months old

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age 2 months to 23 months, first attack of wheezing. Exclusion criteria: Any history of previous wheezing attack(s), congenital heart disease, severe malnutrition, any history of taking zinc sulfate last month and pneumonia
Age
From **1 year** old to **2 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad university of medical sciences
Street address
Daneshgah Street
City
Mashhad
Postal code
Approval date
2007-06-16, 1386/03/26
Ethics committee reference number
86229

Health conditions studied

1

Description of health condition studied
Acute bronchiolitis
ICD-10 code
J21
ICD-10 code description
Acute bronchiolitis

Primary outcomes

1

Description
Clinical manifestations
Timepoint
every day
Method of measurement
Physical exam

2

Description
Recovery
Timepoint
Daily
Method of measurement
Inspection

Secondary outcomes

empty

Intervention groups

1

Description
Syrup of zinc sulfate 1% (1CC per kg) for children below 1 year old and 20 mg elemental zinc for older than 1 year old in case group were administered during hospitalization
Category
Treatment - Drugs

2

Description
The control group was taken placebo. The bottles were similar in size and shape for both case and control groups.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Dr. Farhad Heydarian
Street address
Ghaem hospital, Ahmad abad St.
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ramezani
Street address
Daneshgah St. Ghorashi building
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

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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