

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Name

Farhad Heydarian

###### Name of organization / entity

Mashhad university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1801 2469

###### Email address

heydarianf@mums.ac.ir

##### 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

**City**

Mashhad

**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

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Farhad Heydarian

**Position**

Pediatrician-Associated professor of pediatrics

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

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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### Person responsible for updating data

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**Full name of responsible person**

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**Position**

Pediatrician-Associated professor

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farhad.heydarian@gmail.com

**Web page address**

### 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*