

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Zinc Supplementation Versus Placebo for Bronchiolitis Management in Children: A Comparative Study

Protocol summary

Study aim

To evaluate the efficacy of zinc supplementation compared to a placebo in augmenting standard therapy for the management of bronchiolitis in pediatric patients.

Design

Single blind randomized controlled trial

Settings and conduct

The study was conducted in the patients admitted in Children hospital and university of child health sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria Children with age group 2 - 23 months having and Clinical signs & symptoms of acute bronchiolitis were included Exclusion criteria Children with use of mechanical ventilation in neonates or History of prematurity, Recent use of antibiotic, Congenital heart and lung disease, Down syndrome, Respiratory failure signs, Immunodeficiency, Previous wheezing episodes history, Family history of allergies and/or asthma, Metabolic or neurological diseases, Zinc intake during the previous one month were excluded

Intervention groups

One group received 1% zinc sulphate (20mg/5ml) orally (0.5 cc/kg in children with age below one year and 5cc (20 mg) in children with age above 1 year). Other group received placebo treatment (5%-100% glucose water and oral flavoring). General appearance, smell, color and taste of the Zinc and placebo syrups was similar.

Main outcome variables

Patients were evaluated for the clinical sign & symptoms including wheezing, rhinorrhea, cyanosis, subcostal and intercostal retraction, tachypnea, fever and nasal flaring. pre-designed Performa was used to record findings.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230729058959N1**

Registration date: **2023-09-14, 1402/06/23**

Registration timing: **retrospective**

Last update: **2023-09-14, 1402/06/23**

Update count: **0**

Registration date

2023-09-14, 1402/06/23

Registrant information

Name

Hafiz sheraz Arshad

Name of organization / entity

Link Medical Institute-The Journal of Health and Rehabilitation Research (JHRR)

Country

Pakistan

Phone

+92 300 4009429

Email address

editor@jhrlmc.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-15, 1401/09/24

Expected recruitment end date

2023-05-30, 1402/03/09

Actual recruitment start date

2022-12-15, 1401/09/24

Actual recruitment end date

2023-06-15, 1402/03/25

Trial completion date

2023-06-15, 1402/03/25

Scientific title

Zinc Supplementation Versus Placebo for Bronchiolitis Management in Children: A Comparative Study

Public title

Zinc Supplementation Versus Placebo for Bronchiolitis Management in Children: A Comparative Study

2022-08-20, 1401/05/29

Ethics committee reference number
576

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with age group 2 - 23 months having Clinical signs & symptoms of acute bronchiolitis

Exclusion criteria:

Use of mechanical ventilation in neonates or History of prematurity Recent use of antibiotic Congenital heart and lung disease Down syndrome Respiratory failure signs Immunodeficiency Previous wheezing episodes history Family history of allergies and/or asthma Metabolic or neurological diseases Zinc intake during the previous one month

Age

From **2 months** old to **23 months** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **102**

Actual sample size reached: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Single blind randomized controlled trial

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blind randomized controlled trial

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board

Street address

Saeed Ahmad Awan Mohallah Qasorian Qila Didar
Singh Gujranwala

City

Gujranwala

Postal code

50250

Approval date

Health conditions studied

1

Description of health condition studied

Bronchiolitis

ICD-10 code

J21

ICD-10 code description

Acute bronchiolitis

Primary outcomes

1

Description

wheezing

Timepoint

24, 48, 72, 96 and 120 hours

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children hospital and university of child health sciences

Full name of responsible person

Dr. Ali Hamza Arshad

Street address

Children hospital and university of child health sciences

City

Lahore

Postal code

54000

Phone

+92 333 4379801

Email

Drhamzaarshad92@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Children hospital and university of child health sciences

Full name of responsible person

Dr Ali Hamza Arshad

Street address

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City

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Email

Drhamzaarshad92@gmail.com

Grant name

NA-Self

Grant code / Reference number

NA-Self

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

Yes

Title of funding source

Children hospital and university of child health sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Children hospital and university of child health sciences

Full name of responsible person

Dr Ali Hamza Arshad

Position

Medical Officer

Latest degree

Master

Other areas of specialty/work

Pediatrics

Street address

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Person responsible for scientific inquiries

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Children hospital and university of child health sciences

Full name of responsible person

Dr Ali Hamza Arshad

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Person responsible for updating data

Contact**Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

NA

When the data will become available and for how long

NA

To whom data/document is available

NA

Under which criteria data/document could be used

NA

From where data/document is obtainable

NA

What processes are involved for a request to access data/document

NA

Comments

NA