

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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**

Children hospital and university of child health sciences

**City**

Lahore

**Postal code**

54000

**Phone**

+92 333 4379801

**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**

Children hospital and university of child health sciences

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Lahore

**Province**

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## Person responsible for scientific 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

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## Person responsible for updating data

**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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**Email**

Drhamzaarshad92@gmail.com

**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