Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 sued 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

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+92 300 4009429

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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

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
2022-08-20, 1401/05/29

Ethics committee reference number
576

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
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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
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Person responsible for updating data

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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