

# Efficacy of zinc (given as an adjunct) in the treatment of severe and very severe pneumonia in hospitalised children 2 to 24 months of age

<b>Submission date</b> 17/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/07/2013	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Olivier Fontaine

### Contact details

The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO)  
20 Avenue Appia  
Geneva  
Switzerland  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

NCH 05004; C6-181-508

# Study information

## Scientific Title

### Study objectives

Daily oral administration of 20 mg of elemental zinc given in addition to standard antimicrobial therapy in hospitalised children aged 2 to 35 months admitted with severe pneumonia reduces the proportion of treatment failures by 30% as compared to children receiving standard antimicrobial therapy alone.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approval received from:

1. Ethics Committee of the All India Institute of Medical Sciences on 03/03/2006 (ref: A-01: 03/02/2006)
2. Office of the Medical superintendent, Deen Dayal Upadhyay Hospital on 29/08/2006 (ref: F.19 (21)06-DDUH/LIB./9382)
3. Institutional ethics committee of Lady Hardinge Medical College & Associated Hospitals on 21/09/2006
4. World Health Organization Research Ethics Review Committee (WHO ERC) on 22/02/2006

### Study design

Randomised, placebo controlled, clinical trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Severe and very severe pneumonia

### Interventions

Children will be randomised to receive 20 mg of elemental zinc or placebo each day until discharge, and to be completed at home for a total period of 14 days.

Principal investigator:

Shinjini Bhatnagar

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Second Sponsor:  
Johns Hopkins Bloomberg School of Public Health  
615 N Wolfe Street  
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MD 21205-2179  
United States of America

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Elemental zinc

### **Primary outcome measure**

Primary outcome measure will be the proportion of children who become treatment failures on standard antimicrobial therapy.

### **Secondary outcome measures**

1. Time to recovery from severe pneumonia
2. Time to discharge (complete cessation of clinical signs of pneumonia)

### **Overall study start date**

01/09/2006

### **Completion date**

31/12/2008

## **Eligibility**

### **Key inclusion criteria**

Children 2 months and up to 24 months of age presenting with a cough or difficult breathing of less than seven days duration with:

1. Fast breathing:
  - 1.1. Greater than 50 breaths per minute in children less than 24 months
  - 1.2. Greater than 40 breaths per minute in children 24 to 35 months
2. Crepitations (on auscultation)
3. Presence of chest indrawing or any general danger sign, i.e., lethargy or inability to drink or central cyanosis (defined as severe pneumonia)

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

2 Months

**Upper age limit**

24 Months

**Sex**

Both

**Target number of participants**

492

**Key exclusion criteria**

Children with any of the following features will be excluded:

1. Congenital malformations, e.g., hydrocephalus, structural Central Nervous System (CNS) malformation
2. Known structural defects, which interfere with feeding, for example:
  - 2.1. Cleft palate
  - 2.2. Oesophageal abnormalities
  - 2.3. Intestinal atresia and stenosis
  - 2.4. Malrotation of the gut
  - 2.5. Anorectal malformation
3. Subjects requiring ventilation or ionotropic support
4. Known inborn error of metabolism
5. Chronic disorders of other organs, e.g., neonatal cholestasis, chronic renal failure, pre-existing seizure disorder
6. Infants born of known Human Immunodeficiency Virus (HIV) mothers
7. Congenital heart disease
8. Known case of bronchial asthma
9. Active measles (fever and rash)
10. Severe malnutrition requiring separate medical attention
11. Children receiving zinc supplements
12. Children documented to have received intravenous antimicrobials for more than 48 hours for current illness

**Date of first enrolment**

01/09/2006

**Date of final enrolment**

31/12/2008

**Locations****Countries of recruitment**

India

Switzerland

**Study participating centre**

The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO)

Geneva

Switzerland

CH-1211

## **Sponsor information**

**Organisation**

The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO)  
(Switzerland)

**Sponsor details**

20 Avenue Appia

Geneva

Switzerland

CH-1211

**Sponsor type**

Research organisation

**Website**

<http://www.who.int/child-adolescent-health/>

**ROR**

<https://ror.org/01f80g185>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

The Department of Child and Adolescent Health (CAH)/World Health Organisation (WHO)  
(Switzerland)

**Funder Name**

John Hopkins University (JHU) (USA)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2013		Yes	No