

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

Submission date 17/04/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/04/2007	Overall study status Completed	☐ Protocol
Last Edited 17/07/2013	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ 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
CH-1211

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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

Centre For Diarrhoeal Diseases and Nutrition Research

Department of Paediatrics

All India Institute of Medical Sciences

New Delhi-110029

India

Tel.: +91 (0)11 2659 3290

Fax: +91 (0)11 2658 8822

Email: shinjini_bhatnagar@rediffmail.com

Second Sponsor:

Johns Hopkins Bloomberg School of Public Health

615 N Wolfe Street

Baltimore
MD 21205-2179
United States of America

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Elemental zinc

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 months

Upper age limit

24 months

Sex

All

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)

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**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?
Results article	results	01/06/2013		Yes	No