ISRCTN48954234 https://doi.org/10.1186/ISRCTN48954234

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

Registration date
23/04/2007

Overall study status
Completed

Last Edited
17/07/2013

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO)
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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
Baltimore
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 Viurs (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
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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?
Results article	results	01/06/2013		Yes	No