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# Efficacy of zinc as an adjunct therapy in the management of severe pneumonia among Gambian children

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| **Submission date**<br>14/10/2005 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>21/10/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>07/01/2021 | **Condition category**<br>Respiratory | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
SCC967

# Study information

### Scientific Title
Efficacy of zinc as an adjunct therapy in the management of severe pneumonia among Gambian children

### Study objectives
Zinc supplementation given to Gambian children as an adjunct therapy in severe or very severe pneumonia will be associated with more rapid recovery.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Added as of 14/09/2007: The trial was approved by the Gambia Government/MRC Laboratories Joint Ethics Committee on 5 October 2005. (ref: SCC967)

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Severe and very severe pneumonia defined clinically

### Interventions
Interventions amended as of 17/09/2007:

Zinc sulphate or placebo. Zinc will be given once daily orally at a dose of 10 mg in those aged 2-11 months and 20 mg in those 12-59 months. All participants will receive zinc or placebo for 7 days, while a randomly selected subgroup will receive 6 months supplementation.

Please note that this amendment reflects an error in the information provided at time of registration and not a change in protocol; zinc sulphate has been used throughout the trial.

Interventions provided at time of registration:

Zinc acetate or placebo. Zinc will be given once daily orally at a dose of 10 mg in those aged 2-11 months and 20 mg in those 12-59 months. All participants will receive zinc or placebo for 7 days, while a randomly selected subgroup will receive 6 months supplementation.

### Intervention Type
Supplement

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Zinc supplementation

### Primary outcome measure
Treatment failure at 5 days

### Secondary outcome measures
The following will be assessed after 6 months supplementation of zinc or placebo in a subgroup:
1. Time to resolution of signs of severe and very severe pneumonia
2. Length of admission
3. Height
4. Multi-antigen skin testing

### Overall study start date
24/10/2005

### Completion date
31/03/2011

## Eligibility

### Key inclusion criteria
Prior to 18/10/10:
Children aged 2-59 months presenting with severe or very severe pneumonia to the MRC Hospital or the Royal Victoria Teaching Hospital, Banjul.

Modified on 18/10/10:
'Children aged 2-59 months presenting with severe or very severe pneumonia to the MRC Hospital, the Royal Victoria Teaching Hospital, Banjul, and the health centres at Fajikunda, Brikama, Serekunda and Basse.

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
2 Months

**Upper age limit**
59 Months

**Sex**
Not Specified

**Target number of participants**
600

**Total final enrolment**
604

**Key exclusion criteria**
Children with severe malnutrition or signs of systemic infection other than pneumonia

**Date of first enrolment**
24/10/2005

**Date of final enrolment**
31/03/2011

# Locations

**Countries of recruitment**
Gambia

**Study participating centre**
**MRC Laboratories**
Banjul
Gambia
000 000

# Sponsor information

**Organisation**
Medical Research Council (UK)

**Sponsor details**
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
corporate@headoffice.mrc.ac.uk

**Sponsor type**
Research council

**Website**
http://www.mrc.ac.uk

**ROR**
https://ror.org/03x94j517

# Funder(s)

**Funder type**
Research council

**Funder Name**
Medical Research Council (UK)

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# 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 | 01/06/2018 | 07/01/2021 | Yes | No |