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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Treatment failure at 5 days

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 months

Upper age limit
59 months

Sex
Not Specified

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
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Sponsor information

Organisation
Medical Research Council (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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