

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	☒ Prospectively registered ☐ Protocol
Registration date 21/10/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/01/2021	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Howie

Contact details
MRC Laboratories
P.O. Box 273
Banjul
Gambia
000 000
+220 4494438
showie@mrc.gm

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)

Primary study design

Interventional

Study design

Randomised controlled trial

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

000 000

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