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Efficacy of zinc or iron supplementation during first three years of life in preventing mortality in Zanzibar (Tanzania)

Submission date 27/07/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/07/2004	**Overall study status** Completed	
Last Edited 28/02/2014	**Condition category** Signs and Symptoms	

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
WHO/CAH ID 00003

Study information

Scientific Title

Study objectives
To assess the effect of iron and folic acid supplementation on severe morbidity and mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the World Health Organization (WHO) ethical committee (Sub Committee on Research Involving Human Subjects [SCRIHS]) in the year 2000.

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 morbidity and mortality

Interventions
5 mg zinc or placebo/day for infants less than 6 months and 10 mg/day for infants older than 6 months. All children will receive daily vitamin A supplement (one tablet for infants greater than 6 months and half tablet for infants less than 6 months).

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Zinc, vitamin A supplementation

Primary outcome measure

Serious adverse events (a composite of hospital admissions and all-cause deaths)

Secondary outcome measures
1. Death during follow-up or within 30 days of stopping supplementation
2. Hospital admission to any of the five public hospitals in Pemba

Overall study start date
01/01/2003

Completion date
19/08/2003

Eligibility

Key inclusion criteria
1. Children aged 1 to 35 months
2. Resident of the Pemba Island and likely to remain in the area during the study period
3. Parents consenting to participate in the trial

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Months

Upper age limit
35 Months

Sex
Both

Target number of participants
24076 children (at time of final enrolment)

Key exclusion criteria
1. Children unable to swallow
2. Children hospitalised or receiving therapeutic multivitamins supplements are only recruited once discharged from hospital or supplement therapy is stopped
3. Children with clinically severe malnutrition will be re-evaluated after completion of the rehabilitation

Date of first enrolment
01/01/2003

Date of final enrolment
19/08/2003

Locations

Countries of recruitment
Switzerland

Tanzania

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
The Department of Child and Adolescent Health and Development (CAH)/World Health Organization (WHO) (Switzerland)

Sponsor details
20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
The Department of Child and Adolescent Health and Development (CAH)/World Health Organization (WHO) (Switzerland)

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	14/01/2006		Yes	No
Results article	results	17/03/2007		Yes	No
Results article	results	01/09/2013		Yes	No