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Micronutrients and enteric infections in African children: the effect of prophylactic micronutrient supplementation on morbidity and growth in human immunodeficiency virus infected and human immunodeficiency virus-uninfected children in South Africa

Submission date	Recruitment status	[_] Prospectively registered
30/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/01/2019	Infections and Infestations	

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
NCT00133419

Secondary identifying numbers
5U01 AI058371-05 (grant number); NIH/NIAD

Study information

Scientific Title
Micronutrients and enteric infections in African children: the effect of prophylactic micronutrient supplementation on morbidity and growth in human immunodeficiency virus infected and human immunodeficiency virus-uninfected children in South Africa

Study objectives
Objective:
To compare the effect of three micronutrient supplements:
1. Vitamin A only,
2. Vitamin A and zinc,
3. A micronutrient mixture containing vitamins A, B, C, D, E, K, and calcium, copper, folate, iodine, iron, magnesium and zinc, on prevalent days of diarrhoea in three groups of children:
a. Human Immunodeficiency Virus (HIV)-infected children
b. HIV-uninfected children born to HIV-infected women
c. HIV-uninfected children born to women without HIV infection

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
A randomised, double blind, clinical controlled trial with three arms

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

Human Immunodeficiency Virus (HIV)

Interventions
Children from each of the HIV status groups will be individually randomised to one of the three multivitamin/micronutrient arms:
1. Vitamin A only
2. Vitamin A and zinc
3. A micronutrient mixture containing vitamins A, B, C, D, E, K, and calcium, copper, folate, iodine, iron, magnesium and zinc

Randomisation will occur in blocks of six within each of the HIV status groups. This will result in assigning a pre-coded box filled with blister packets of seven micronutrient tablets each. Each child will use tablets from that same box throughout the study. Each type of tablet will appear and taste identical to ensure blinding of both mothers and field staff. The interval between testing and randomisation may vary depending on the time required to obtain HIV testing results. All children will, however, start their respective supplement at six months of age (+/- 14 days) and will continue with the supplements until they are 24 months of age (i.e. for approximately 18 months). Monitoring will continue throughout this time to determine the long-term impact of each supplementation.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Micronutrient supplementation

Primary outcome measure
The primary outcome measure is prevalent days of diarrhoea per child during the 18 months that children will receive supplements (from six to 24 months of age). Comparisons will be stratified by HIV status, and all three micronutrient regimens will be compared within these strata.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/07/1999

Completion date
30/06/2005

Eligibility

Key inclusion criteria
1. Infants aged four to six months (stratified by HIV status)
2. Able to take oral preparations
3. Parent/guardian able to give consent

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Months

Upper age limit
6 Months

Sex
Not Specified

Target number of participants
516

Key exclusion criteria
1. Documented micronutrient supplementation other than vitamin A in the preceding month
2. Less than 60% of mean weight for age by National Center for Health Statistics (NCHS) guidelines (micronutrient intervention obligatory according to World Health Organisation [WHO] guidelines for management of severely malnourished children)
3. Persistent diarrhoea (more than seven days) at the time of study enrolment
4. Exclusive breastfeeding
5. Infants in whom a second confirmatory HIV test cannot be obtained (when required)
6. Co-enrolment of the infant in other clinical intervention trials e.g. antibiotic or vaccine trials

Date of first enrolment
01/07/1999

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
South Africa

Study participating centre
Africa Centre for Health and Population Studies
Mtubatuba
South Africa
3935

Sponsor information

Organisation
National Institute of Allergy and Infectious Diseases (NIAID) (USA)

Sponsor details
International Tropical Disease Research Network
Division of Microbiology and Infectious Diseases (DMID)
Room 5067
6610 Rockledge Drive
Bethesda
United States of America
20892

Sponsor type
Government

Website
http://www.niaid.nih.gov/

ROR
https://ror.org/043z4tv69

Funder(s)

Funder type
Government

Funder Name
National Institute of Allergy and Infectious Diseases (NIAID) (USA)

Alternative Name(s)
Instituto Nacional de Alergias y Enfermedades Infecciosas, National Institute of Allergy & Infectious Diseases, NIAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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	27/06/2007	28/01/2019	Yes	No
Results article	results	01/07/2009	28/01/2019	Yes	No
Results article	results	18/03/2010	28/01/2019	Yes	No