

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

30/03/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

30/03/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

28/01/2019

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof M L Bennish

Contact details

Africa Centre for Health and Population Studies

P.O. Box 198

Mtubatuba

South Africa

3935

+27 (0)35 550 7502

mbennish@africacentre.ac.za

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