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Vitamin and mineral supplementation in reducing morbidity in Human Immunodeficiency Virus (HIV)-infected children in developing countries: an efficacy study

Submission date 21/11/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/12/2007	**Overall study status** Completed	
Last Edited 07/12/2007	**Condition category** 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

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Mnuts/supps/HIV/children

Study objectives
Micronutrient deficiencies contribute to immune dysfunction and can lead to increased infectious morbidity in Human Immunodeficiency Virus (HIV)-1-infected children. We hypothesised that micronutrient supplementation could reduce infectious morbidity in HIV-1-infected children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Research Ethics Committee (REC) of the University of Cape Town on 03/12/2001 (ref: RECRES 118/2001).

Study design
Prospective, double-blind randomised, placebo-controlled clinical 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
Micronutrient supplementation of HIV-1-infected children

Interventions
Patients are randomised into one of the three arms:
Group A - placebo
Group B - trace element supplement
Group C - high dose zinc supplement (3 mg/kg elemental zinc)

Trial drugs are given orally daily over six months and children are seen monthly for 12 weeks from start to end of the study.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin and mineral supplementation

Primary outcome measure
Relative frequency of adverse or serious infective episodes, or death.

Secondary outcome measures
1. Viral load and CD4 count changes
2. Biochemical variables such as micronutrient levels measures
3. Relative frequency of minor infective episodes

Overall study start date
23/04/2002

Completion date
26/11/2004

Eligibility

Key inclusion criteria
1. Clinically stable (not acutely ill)
2. Vertically transmitted HIV-1 infected children
3. Attending the Infectious Diseases Clinic at Red Cross Children's Hospital
4. Aged six months to six years

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
6 Years

Sex
Not Specified

Target number of participants

495

Key exclusion criteria
1. HIV-infected children aged less than six months
2. Children with an intercurrent infection or axillary temperature of more than 38°C
3. Children with any invasive opportunistic infection including tuberculosis
4. Children with bronchiectasis
5. Children who had received high dose vitamin A, trace elements or zinc supplements within the preceding eight weeks
6. Children recently hospitalised within the preceding six weeks

Date of first enrolment
23/04/2002

Date of final enrolment
26/11/2004

Locations

Countries of recruitment
South Africa

Study participating centre
Ambulatory Paediatrics
Cape Town
South Africa
7700

Sponsor information

Organisation
Secure-The-Future Bristol-Myers Squibb (South Africa)

Sponsor details
Bristol-Myers Squibb
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Sponsor type

Industry

Website
http://www.bms.com

Funder(s)

Funder type
Industry

Funder Name
Secure-the-Future Bristol-Myers Squibb (South Africa) (ref: RES094/02)

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