

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	<input type="checkbox"/> Prospectively registered
Registration date 07/12/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/12/2007	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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7700

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

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

HIV Research Institute

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Gauteng

South Africa

2008

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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