

Safety of zinc supplementation in HIV-infected children

Submission date 20/03/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 28/04/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 27/10/2009	Condition category Infections and Infestations	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym

ZnsuppHIVChildren

Study objectives

Zinc deficiency is common in human immunodeficiency virus (HIV)-infected children and contributes to immune dysfunction; zinc supplementation can improve immune function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Research Ethics Committee (REC) of the University of Cape Town on 19/04/2001, reference number: 004/2001

Study design

Double-blind randomised placebo-controlled three-arm trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Zinc supplementation of HIV-1 infected children

Interventions

Patients are randomised into one of the three arms:

Group A - placebo

Group B - low dose zinc supplement

Group C - high dose zinc supplement

Trial drugs are given orally daily over 6 weeks and children are seen weekly for 12 weeks from start to end of the study.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Zinc

Primary outcome(s)

1. No increase in viral loads
2. No reduction in CD4 counts
3. No deaths
4. Laboratory indicators of safety

Key secondary outcome(s))

1. An improvement in immune function on zinc supplementation
2. A reduction in infective events
3. A reduction in admissions to hospital

Completion date

31/07/2003

Eligibility

Key inclusion criteria

1. Clinically stable
2. Vertically transmitted HIV-1 infected children
3. Attending the Infectious Diseases Clinic at Red Cross Children's Hospital
4. Aged 6 months to 6 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

6 years

Sex

All

Key exclusion criteria

1. HIV-infected children aged less than 6 months
2. Children with an intercurrent infection or axillary temperature of $>38^{\circ}\text{C}$
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 8 weeks
6. Children recently hospitalised

Date of first enrolment

01/06/2002

Date of final enrolment

31/07/2003

Locations

Countries of recruitment

South Africa

Study participating centre

Ambulatory Paediatrics

Cape Town

South Africa

7700

Sponsor information

Organisation

University of Cape Town, The Child Health Unit (South Africa)

ROR

<https://ror.org/03p74gp79>

Funder(s)

Funder type

University/education

Funder Name

Internally funded trial - The Child Health Unit, University of Cape Town (South Africa)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration