ISRCTN56894409 https://doi.org/10.1186/ISRCTN56894409

Safety of zinc supplementation in HIV-infected children

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Heloise Buys

Contact details
Ambulatory Paediatrics
School of Child and Adolescent Health
Red Cross Children's Hospital
Klipfontein Road
Rondebosch
Cape Town
South Africa
7700
hbuys@ich.uct.ac.za

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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

Overall study start date
01/06/2002

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

Age group
Child

Lower age limit
6 Months

Upper age limit
6 Years

Sex
Both

Target number of participants
Convenience sample of 39 eligible children

Key exclusion criteria

1. HIV-infected children aged less than 6 months
2. Children with an intercurrent infection or axillary temperature of >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 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)

Sponsor details
Sawkins Road
Rondebosch
Cape Town
South Africa
7700

Sponsor type
University/education

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

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