

Safety and benefit of iron supplementation in HIV infected children

Submission date 14/08/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/08/2013	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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
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Study information

Scientific Title
Double-blind, randomised, placebo-controlled trial of iron supplementation in HIV-infected Malawian children: Is it safe and beneficial?

Acronym

HI Study

Study objectives

We hypothesise that iron supplementation in anaemic HIV infected children is associated with a positive haematological response without an increased risk of morbidity, HIV disease progression and death.

Ethics approval required

Old ethics approval format

Ethics approval(s)

College of Medicine Research and Ethics Committee, University of Malawi. Date of approval: 28 /07/2008 (ref: P.03/08/623)

Study design

Double-blind, randomised, placebo-controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

HIV and iron deficiency

Interventions

The participants will be randomly allocated to the following arms:

Arm 1: Supplementation of oral multi-vitamins with iron, (3 mg/kg body weight/day) for 3 months

Arm 2: Oral multi-vitamins alone for 3 months

Total duration of interventions: 3 months

Total duration of follow-up: 6 months

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Iron supplementation

Primary outcome(s)

The incidence of all-cause sick visits during the trial and follow up period.

Key secondary outcome(s)

1. Incidence of all-cause hospitalisations during the trial and follow up period
2. Incidence of haemoglobin <7 g/dl during the follow up period of 6 months
3. Laboratory diagnosis of acquired immune deficiency syndrome (AIDS) or clinical stage IV disease, patient requiring highly active antiretroviral treatment (HAART)

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Both males and females, age 6-59 months
2. Presence of moderate anaemia (haemoglobin 7-9.9 g/dl)
3. HIV positive
4. Mean corpuscular volume (MCV) ≤ 73 f/l (for children from 2-5 years); ≤ 67 f/l (for children <2 years)
5. Informed consent by parent/guardian

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

59 months

Sex

All

Key exclusion criteria

1. Patients already on nutritional supplements
2. Presence of gross congenital, cognitive or neuro-developmental anomalies
3. Children with malnutrition requiring supplementary feeding; weight-for-height less than 80% of expected; presence of bipedal oedema
4. Patients with haemoglobin <7 g/dl or ≥ 10 g/dl

Date of first enrolment

15/09/2008

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Malawi

Study participating centre

Malawi-Liverpool Wellcome Trust

Blantyre

Malawi

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Sponsor information

Organisation

Liverpool School of Tropical Medicine (UK)

ROR

<https://ror.org/03svjbs84>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands-African partnership for capacity development and clinical interventions against poverty-related diseases (NACCAP) (The Netherlands)

Results and Publications

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	01/12/2013		Yes	No

[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes