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Safety and benefit of iron supplementation in HIV infected children

Submission date	Recruitment status	[_] Prospectively registered
14/08/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/08/2013	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.nwo.nl/nwohome.nsf/pages/NWOA_6LRBKV_Eng

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
15/09/2008

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

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
1,260

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)

Sponsor details
Pembroke Place
Liverpool
England
United Kingdom
L3 5QA

Sponsor type
University/education

Website
http://www.liv.ac.uk/lstm

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2013		Yes	No