Safety and benefit of iron supplementation in HIV infected children

Submission date	Recruitment status No longer recruiting	Prospectively registered		
14/08/2008		☐ Protocol		
Registration date 30/09/2008	Overall study status Completed	Statistical analysis plan		
		[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

Contact name

Dr Kamija Phiri

Contact details

Malawi-Liverpool Wellcome Trust College of Medicine University of Malawi PO Box 30096 Blantyre Malawi 3

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 3

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