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A pilot study on the use of low dose erythropoietin in the management of human immunodeficiency virus (HIV) associated anaemia in Uganda

Submission date
20/06/2007

Registration date
06/08/2007

Last Edited
02/09/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
HS 103

Study information

Scientific Title

Acronym
The Wepox study

Study objectives
Erythropoietin is efficacious in improving the haemoglobin among anaemic HIV+ individuals at a lower than the currently recommended dose of 40,000 IU per week or 100 - 300 IU/Kg three times per week.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Ethics committee of the Faculty of Medicine, Makerere University on 29th December 2005. Renewed on the 23rd April 2007 and will expire on 23rd October 2007.
2. Uganda National Council for Science and Technology (UNCST) on 18th January 2006. Renewed on the 10th May 2007 and will expire on the 13th April 2008 (ref: HS103).

Study design
Open label randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
HIV associated anaemia

Interventions
Each participant will be randomised to one of the following four groups:
1. Intervention group 1: Haematinics (one capsule orally once daily) and erythropoietin (Wepox) 2000 IU three times per week subcutaneously for 4 weeks
2. Intervention group 2: Haematinics (one capsule orally once daily) and erythropoietin (Wepox) 4000 IU once a week subcutaneously for 4 weeks
3. Intervention group 3: Haematinics (one capsule orally once daily) and erythropoietin (Wepox) 2000 IU once a week subcutaneously for 4 weeks
4. Control group: Haematinics (one capsule orally once daily) for 4 weeks

The haematinic capsule contains 305 mg ferrous fumarate equivalent to 100 mg elemental iron, 0.75 mg folic acid, 5 micrograms cyanocobalamin, 75 mg ascorbic acid and 5.0 mg zinc sulphate.

Interim analysis of this study will be carried out in July 2007. Final evaluation of the study will be carried out on completion of the study enrolment and follow-up, but the latter may be influenced by the results of the interim analysis.

Intervention Type

Other

Phase
Not Specified

Primary outcome(s)
Change in haemoglobin, measured at week 0 and end of week 4.

Key secondary outcome(s))
1. Quality of life improvement, measured at week 0 and end of week 4 using a visual analogue scale (LASA) and the Medical Outcomes Study HIV Health Survey (MOSHIV) instrument
2. Adverse events

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. Documented HIV positive
2. Grade 1 and 2 anaemia
3. Informed consent
4. Age 18 to 65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Recent blood loss
2. Active opportunistic infection
3. Presence of fever at the time of enrolment
4. Pregnancy
5. Cancer chemotherapy
6. Severe microcytosis
7. Systemic hypertension
8. Known allergy to erythropoietin

Date of first enrolment

01/03/2006

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
Uganda

Study participating centre
Plot 893 Ring Road
Kampala
Uganda
P.O. Box 10005

Sponsor information

Organisation
Star Pharmaceuticals Ltd (Uganda)

Funder(s)

Funder type
Industry

Funder Name
Star Pharmaceuticals Uganda Ltd (Uganda) - local representative for Wockhardt

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration