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A nutritional supplement for human immunodeficiency virus (HIV) antibody positive patients at Mengo Hospital, Kampala, Uganda

Submission date
21/07/2005

Registration date
23/08/2005

Last Edited
14/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] 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
N/A

Study information

Scientific Title

Study objectives
A nutritional supplement including selenium as L-selenomethione 600 mcg for the first month followed by 400 mcg for the duration of the study, the 3 amino acids (N-Acetylcysteine, L-glutamine, and Hydroxytryptophane), vitamins (A, B, C, E), and trace minerals will increase CD4 counts and improve quality of life over 48 weeks for HIV+ patients and thereby, delay the need for commencing antiretroviral virus (ARV) therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
HIV antibody positive patients

Interventions
All patients attending the acquired immunodeficiency syndrome (AIDS) clinic at Mengo Hospital will be offered the opportunity to participate. After registration patients will be randomly assigned to 2 groups using a standard list of random numbers. The 'control' group will receive a standard mix of vitamins including A, B, C, E and minerals (excluding selenium). The 'treatment' group will receive the same vitamin mineral mixture plus L-selenomethionine 600 mcg for 4 weeks followed by 400 mcg for the duration and 3 essential amino acids N-Acetylcysteine 360 mg, L-Glutamine 360 mg and Hydroxytrptophane 360 mg. Cd4 counts and Glutathione Peroxidase levels will be measured initially and at weeks 24 and 48. Clinical parameters including symptoms, weight change, opportunistic infections, and quality of life questionnaire will be recorded every 6 weeks.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Selenium as L-selenomethione, the 3 amino acids (N-Acetylcysteine, L-glutamine, and Hydroxytryptophane), vitamins (A, B, C, E), and trace minerals

Primary outcome(s)
1. Change in Cd4 counts and GPx
2. Improved quality of life

Key secondary outcome(s))
1. Delay progression of disease as measured by WHO staging and CD4 counts
2. Delay need to institute ARV therapy

Completion date
01/08/2006

Eligibility

Key inclusion criteria
1. Over 18 years
2. CD4 counts 200-500
3. Reside within 15 km of Mengo Hospital at a fixed address

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. World Health Organisation (WHO) stage 4 disease
2. Pregnant and breast feeding women
3. Patients who have received selenium supplementation in the preceding 3 months
4. Patients currently receiving ARV therapy

Date of first enrolment
01/05/2005

Date of final enrolment
01/08/2006

Locations

Countries of recruitment
Canada

Uganda

Study participating centre
3400 Upper Terrace
Victoria,BC
Canada
V8R 6E6

Sponsor information

Organisation
Friends of Mengo Hospital Canada (Canada)

Funder(s)

Funder type
Charity

Funder Name
Private donations to Friends of Mengo Hospital Canada, a registered Canadian charity and NGO (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration