

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

Submission date 21/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/08/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/09/2009	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

1. Change in Cd4 counts and GPx
2. Improved quality of life

Secondary outcome measures

1. Delay progression of disease as measured by WHO staging and CD4 counts
2. Delay need to institute ARV therapy

Overall study start date

01/05/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

350

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)

Sponsor details

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Sponsor type

Charity

Website

<http://mengofriends.ca/>

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

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