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Impact of Spirulina platensis supplementation on general health status of HIV infected patients in Burkina Faso

Submission date	Recruitment status	[_] Prospectively registered
31/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/08/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/08/2007	Infections and Infestations	[_] 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
Daily Spirulina platensis supplementation can improve clinical, nutritional and immunobiological status of HIV infected patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee of Centre Muraz (Institut de Recherche en Sciences de la Santé [IRSS]), approved on 20 December 2005 (ref: 022/2005/CEI-CM)

Study design
Double-blind randomized 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 / AIDS

Interventions
Group 1: 60 Patients with 200 CD4/µl of peripheric blood or lower (patients who are currently receiving antiretroviral treatment)
Sub-group 1 (30 patients): four capsules (a capsule contains 420 mg of spiruline) three times daily per os (orally) for each patient for 12 months
Sub-group 2 (30 patients): The same number of capsules as in sub-group 1 but placebo instead of active supplement

Group 2: 60 Patients with 200 < CD4 < 400 (patients who are currently receiving antiretroviral treatment)
Sub-group 1 (30 patients): four capsules (a capsule contains 420 mg of spiruline) three times

daily per os for each patient for 12 months
Sub-group 2 (30 patients): The same number of capsules as in sub-group 1 but placebo instead of active supplement

Group 3: 60 Patients with CD4 >400 (some of these patients are currently receiving antiretroviral treatment)
Sub-group 1 (30 patients): four capsules (a capsule contains 420 mg of spiruline) three times daily per os for each patient for 12 months
Sub-group 2 (30 patients): The same number of capsules as in sub-group 1 but placebo instead of active supplement

Each included patient in the trial will be followed up monthly by a physician.
Anthropometric parameters of the participants will be measured monthly and their CD4, viral load, hematological and biochemical parameters will be measured semestrially.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Spirulina platensis

Primary outcome measure
The impact of active daily supplementation of Spirulina platensis on the clinical, nutritional and immunological status of HIV infected patients will be assessed by the following:
1. Measurement of CD4, viral load, hematological and biochemical parameters at the start, 6 and 12 months of trial
2. Monthly measurement of anthropometric parameters

Secondary outcome measures
No secondary outcome measures

Overall study start date
20/05/2006

Completion date
20/01/2008

Eligibility

Key inclusion criteria
1. HIV infected
2. At least 18 years old
3. Willing to be followed up for at least 12 months
4. Informed consent to be provided by the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Patients who do not consent to be involved in the trial
2. Under the age of 18 years
3. Patients who are pregnant
4. Cardiopathy or cancer
5. Currently receiving Spirulina platensis spplementation

Date of first enrolment
20/05/2006

Date of final enrolment
20/01/2008

Locations

Countries of recruitment
Burkina Faso

Study participating centre
Institut de Recherche en Sciences de la Santé
Bobo-Dioulasso
Burkina Faso
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Sponsor information

Organisation
Ministry of Health of Burkina Faso, Drug Directorate (DGPML)

Sponsor details
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Sponsor type
Government

ROR
https://ror.org/03h83vk17

Funder(s)

Funder type
Government

Funder Name
Ministry of Health of Burkina Faso, Drug Directorate (DGPML)

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