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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**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Jean Bosco Ouedraogo

**Contact details**
Institut de Recherche en Sciences de la Santé
Direction Régionale de l'Ouest
399, Avenue de la Liberté
01 BP 545 Bobo-Dioulasso 01
Bobo-Dioulasso
Burkina Faso
545
+226 20 98 18 80
jbouedraogo.irss@fasonet.bf

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
N/A

# Study information

### Scientific Title

### Study hypothesis
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

### Condition
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

### Overall study end date
20/01/2008

## Eligibility

### Participant 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

### Participant 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

### Recruitment start date
20/05/2006

### Recruitment end date
20/01/2008

## Locations

### Countries of recruitment
Burkina Faso

### Study participating centre
**Institut de Recherche en Sciences de la Santé**
Bobo-Dioulasso
Burkina Faso
545

## Sponsor information

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

### Sponsor details
Projet Spiruline Nayalgue
S/C Pr Jean-Baptiste Nikiema
Ouagadougou

Burkina Faso
03 BP 7009 Ouaga
+226 50 32 46 60 / 61
jbnikiema@yahoo.fr

**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