

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

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| Submission date 31/05/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 17/08/2007 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 17/08/2007 | 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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

HIV / AIDS

Interventions

Group 1: 60 Patients with 200 CD4/ μ l 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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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* supplementation

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

545

Sponsor information

Organisation

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

ROR

<https://ror.org/03h83vk17>

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration