

Complementary Alternative Medicine for Reconstitution of CD4 count and Quality of Life in HIV-Infected Patients with Advanced Disease

Submission date 27/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/07/2010	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

Study information

Scientific Title
HIV-Infected Patients with Advanced Disease in treatment with HAART use Complementary Alternative Medicine for Reconstitution of CD4 count and for Improving their Health Related Quality of Life over Time

Study objectives

To describe if complementary alternative medicine (CAM) improves CD4 count and health related quality of life (HRQOL) in subjects presenting low naïve CD4 count and poor CD4 rise despite of good virologic response on highly active antiretroviral treatment (HAART).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethics commission of the Hospital San Juan de Dios approved the study design in August 2007.

Study design

Single centre longitudinal case-control study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

HIV-Infected Patients with Advanced Disease under HAART

Interventions

The same physician will be in charge of the CAM treatment throughout, indicating treatment, controlling its effects, adjusting therapy and also indicating additional controls with the physician in charge of HIV if needed. The controls in the program are every 2 to 8 weeks. CAM will combine different therapeutic aspects:

1. All patients receive homeopathy and Bach-Flowers
2. Some cases will receive phytotherapy, consisting of Engystol®, propolis and/or aloe vera
3. Dietary advice, patients to reduce intake of any artificial substances like sweeteners, colourings and preservatives, and also substances like tobacco and alcohol
4. Patients open to body-mind-medicine will be taught a meditation technique by the CAM physician with creative visualization recovering sensations of health, well-being and peace

The homeopathic medicine is applied according the homeopathic constitutional integrated conception (presented in the 7° Congress of the Federation of Medical Homeopathic Argentinean Associations) whose main feature is that the homeopath has to identify the inner conflict of the patient leading to his current condition.

The medication is prepared at all times in the same homeopathic pharmacy under supervision of the same pharmacist. The patient has to fetch his prescription in the pharmacy.

Results are compared with the patient's CD 4 rise before intervention and the expected behaviour of CD 4 rise in these type of patients.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. CD4 cell count and viral load, measured every 3 months

Viral load was considered undetectable with < 80 UI/mL copies using Nuclisens Easy Q HIV-1, Bio Mérieux test

2. Quality of Life, measured by Medical Outcomes Study Short Form 30 (MOS-SF-30) validated for people infected by HIV, answered privately by the patient every 3 months

Key secondary outcome(s)

1. Incidence of hospitalisation

2. Opportunistic infection

3. Death

4. Side effects of CAM

5. Interaction of HAART and CAM

Completion date

05/06/2012

Eligibility

Key inclusion criteria

1. Any adult patient infected with HIV who has a naïve CD4 count < 200 cell/mL and who, despite > 48 weeks of HAART, keep CD4 < 250 cell/mL

2. Adherent to HAART and to the controls with the physician in charge of treatment of the HIV-condition

3. Patients who modify their HAART regimens are not excluded if plasma HIV-1 RNA levels, remain < 80 copies/mL

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients who use hydroxyurea, IL-2, IFN- α , or the combination of tenofovir and didanosine, which are known to affect CD4 count increases

Date of first enrolment

05/06/2007

Date of final enrolment

05/06/2012

Locations

Countries of recruitment

Chile

Study participating centre

Eliecer Parada 2030, Providencia

Santiago de Chile

Chile

7510931

Sponsor information

Organisation

Hospital San Juan de Dios (Chile)

ROR

<https://ror.org/03mt12903>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital SAn Juan de Dios (Chile) - internal funding

Funder Name

Laboratory Heel (Chile) - provides homeopathic medicine and Engystol

Funder Name

Mr. M Cavieres (Local provider) (Chile) - provides Propolis

Funder Name

Dr. Iris von Hörsten (Chile) - provides the Bach-Flowers

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration