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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/07/2010	**Overall study status** Completed	
Last Edited 08/07/2010	**Condition category** Infections and Infestations	

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
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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
1. Incidence of hospitalisation
2. Opportunistic infection
3. Death
4. Side effects of CAM
5. Interaction of HAART and CAM

Overall study start date
05/06/2007

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

Age group
Adult

Sex
Both

Target number of participants
15 patients from the Hospital San Juan de Dios, Santiago, Chile

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)

Sponsor details
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Sponsor type
Hospital/treatment centre

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

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