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Evaluation of the benefit and the safety of a CD4-guided Highly Active Anti-Retroviral Therapy (HAART) interruption strategy in stable adult Human Immunodeficiency Virus (HIV)-infected patients

Submission date 04/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/05/2007	**Overall study status** Completed	
Last Edited 31/07/2013	**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

Protocol serial number
STOPAR-03

Study information

Scientific Title

Acronym
STOPAR

Study objectives
1. The interruption strategy will have a similar efficacy and safety than the continous Highly Active Anti-Retroviral Therapy (HAART) strategy
2. Human Immunodeficiency Virus (HIV)-chronic infected patients stable under HAART will be able to perform long-term treatment interruptions
3. The appearance of resistance mutations will be similar in both arms (HAART-interruption and HAART-continous treatment), approximately 5% of patients will present virological failure
4. Those patients following long-term HAART-interruption will improve their lipid profile and their anthropometic measures from baseline in comparison to the HAART-continous treatment patients
5. Patients achieving a long-term HAART interruption will have a better quality of life in comparison to those in HAART-continous therapy. However, patients needing to re-start and interrupt treatment frequently could have a worse quality of life than those receiving HAART-continous therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
The trial was approved by the Spanish Drug Agency on the 26th August 2003 (ref: 03-0387).

Study design
Randomised, open, multicentre clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adult HIV-1 infected patients

Interventions
Patients will be randomised to Continue Therapy (CT) or to Therapy Interruption (TI); those treated with a NNRTI will discontinue the drug seven days before the nucleoside backbone. Standard antiretroviral drug doses will be used throughout the study period.

CT arm:
Clinical monitoring including adverse effect and other clinical event assessment, anthropometric measures, and blood tests (routine biochemical, haematology parameters, viral load, CD4 counts, lipid profile) will be performed at month one and every three months thereafter.

TI arm:
The same schedule, plus an extra visit at month two. HAART will be reinitiated if CD4 count

decreases to less than 350 cells/mm^3 and re-discontinued if CD4 is greater than 500 and viral load less than 50 copies/mL for at least three months.

Genotypic resistant tests will be performed in patients with virological failure (confirmed greater than 1000 copies/mL in CT arm and detectable viral load after six-month reintroduction of HAART in TI arm)

Overall follow up will be three years, with interim analyses after one and two years of follow-up.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Highly Active Anti-Retroviral Therapy (HAART)

Primary outcome(s)
Clinical (progression to AIDS, or any of the following HIV-associated clinical infections: oral candidiasis, multimetameric herpes zoster, leishmaniasis), virological (confirmed greater than 1000 copies/mL in CT arm and detectable viral load after six-month reintroduction of HAART in TI arm) or immunologic (confirmed CD4 < 200 cells/uL) failure.

Key secondary outcome(s))
1. Time to failure (assessed by log-rank test)
2. Switch due to toxicity (clinical and laboratory evaluation in every visit)
3. Lipid (total cholesterol, High Density Lipoprotein [HDL], Low Density Lipoprotein [LDL], triglycerides measured in every visit) and body fat changes (by patient and physician clinical observation and anthropometric measures, at baseline and at one, two and three years)
4. Quality of life (assessed by Medical Outcomes Study HIV Health Survey [MOS-HIV] questionnaire at baseline and at one, two and three years)

Completion date
30/05/2008

Eligibility

Key inclusion criteria
1. Adult HIV-1 infected patients treated with HAART (two Nucleoside analogue Reverse Transcriptase Inhibitors [NRTIs] plus a Non-Nucleoside Reverse Transcriptase Inhibitor [NNRTI] or two NRTIs plus one or two Protease Inhibitors [PIs])
2. Stable clinical status without HAART changes in the last six months
3. Undetectable viral load (less than 50 copies/mL) in the last six months
4. CD4 greater than 500 cell/mm^3 in the last three months
5. No more than a previous virological failure leading to HAART modification
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Previous Acquired Immune Deficiency Syndrome (AIDS) (except oesophageal candidiasis, pulmonary tuberculosis, recurrent pneumonia and wasting syndrome)
2. CD4 nadir less than 100 cells/mm^3
3. Positive Hepatitis B surface Antigen (HBsAg) using tenofovir and/or lamivudine
4. Child C-cirrhosis
5. Current therapy with immunosuppressive or immunomodulator drugs (including interleukines and interpheron), corticosteroids or chemotherapy
6. Current and previous treatment with HIV-immunogen drugs
7. Pregnancy or breast feeding
8. Patients included in other clinical trials or experimental studies

Date of first enrolment
28/01/2004

Date of final enrolment
30/05/2008

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitari de Bellvitge
Barcelona
Spain
08907

Sponsor information

Organisation
Spanish AIDS Research Network (Red de Investigacion en SIDA [RIS]) (Spain)

Funder(s)

Funder type
Research organisation

Funder Name
Spanish AIDS Research Network (Red de Investigacion en SIDA [RIS]) (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2013		Yes	No