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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
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.

## Secondary outcome measures
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)

## Overall study start date
28/01/2004

## 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

### Age group
Adult

### Sex
Not Specified

### Target number of participants
170 patients (85 patients by arm)

### 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)

**Sponsor details**
Instituto de Salud Carlos III
C/Sinesio Delgado Nº 6
Madrid
Spain
28029

**Sponsor type**
Research organisation

**Website**
http://www.retic-ris.net/default_principal.asp?idx=&cidioma=2

# Funder(s)

**Funder type**
Research organisation

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

# 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

## Study outputs

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