

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

Registration date

16/05/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

31/07/2013

Condition category

Infections and Infestations

☐ Individual participant data

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

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 continuous 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-continuous treatment), approximately 5% of patients will present virological failure
4. Those patients following long-term HAART-interruption will improve their lipid profile and their anthropometric measures from baseline in comparison to the HAART-continuous treatment patients
5. Patients achieving a long-term HAART interruption will have a better quality of life in comparison to those in HAART-continuous therapy. However, patients needing to re-start and interrupt treatment frequently could have a worse quality of life than those receiving HAART-continuous 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/mm³ 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, multimeric 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/mm³ 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/mm³
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 interferon), 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 N° 6
Madrid
Spain
28029

Sponsor type

Research organisation

Website

http://www.retic-ris.net/default_principal.asp?idx=&cidoma=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