Randomised open multicentre trial comparing stavudine versus abacavir, both combined with lamivudine/efavirenz, in Human Immunodeficiency Virus (HIV) infected antiretroviral naïve patients

Submission date	Recruitment status	Prospectively registered		
20/10/2005	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/11/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
20/11/2007	Infections and Infestations			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Daniel Podzamczer

Contact details

Infectious Disease Service
Hospital Universitari de Bellvitge
c/Feixa Llarga s/n
L'Hospitalet
Barcelona
Spain
08907
dpodzamczer@csub.scs.es

Additional identifiers

Protocol serial number

ARV/01

Study information

Scientific Title

Acronym

ABCDE study

Study objectives

To assess lipoatrophy, other toxicities, and efficacy associated with abacavir as compared with stavudine in HIV-infected antiretroviral-naive patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised open multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Human immunodeficiency virus (HIV) infection

Interventions

Patients will centrally be stratified according to HIV-1 RNA greater than or less than or equal to 30,000 copies/ml and CD4 counts greater than or less than or equal to 200 cells/ μ l; and randomised to one of these arms:

- 1. Abacavir 300 mg twice a day (bid), plus lamivudine 150 mg bid, plus efavirenz 600 mg once a day (qd)
- 2. Stavudine 30 40 mg bid (according to less than or more than 60 kg body weight) plus lamivudine and efavirenz at the same doses as group 1

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Stavudine, abacavir

Primary outcome(s)

Proportion of patients with lipoatrophy as assessed by physician and patient observation at 96 weeks.

Key secondary outcome(s))

- 1. Virological, clinical and immunological efficacy
- 2. Tolerability

Completion date

15/01/2004

Eligibility

Key inclusion criteria

- 1. HIV positive confirmed by Western blot
- 2. Adult 18 70 years
- 3. No previous antiretroviral therapy
- 4. HIV-1 Ribonucleic Acid (RNA) greater than 1500 copies/ml (Polymerase Chain Reaction [PCR], Nucleic Acid Sequence Based Amplification [NASBA] or branched-chain Deoxyribonucleic Acid [bDNA]) within 12 weeks prior to study initiation
- 5. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Prior antiretroviral therapy
- 2. Concomitant participation in another clinical trial
- 3. Signs of hepatic cirrhosis
- 4. Any of the following laboratory parameter alterations:
- 4.1. Alanine aminotransferase (ALT) and/or Aspartate aminotransferase (AST) greater than 5 times above the normal values
- 4.2. Creatinine clearance less than 50 ml/min
- 4.3. Amylases greater than 3 times above normal values
- 4.4. Hemoglobin less than 8 mg/dl
- 4.5. Neutrophils less than 500/µl
- 4.6. Platelets less than 30,000/µl
- 5. Pregnancy

- 6. Contraindicated drugs
- 7. Active infection within the last 4 weeks
- 8. Treatment for neoplasms

Date of first enrolment

15/01/2001

Date of final enrolment

15/01/2004

Locations

Countries of recruitment

Spain

Study participating centre Infectious Disease Service

Barcelona Spain 08907

Sponsor information

Organisation

Network of Research on AIDS (Red de Investigacion en SIDA [RIS]) (Spain)

Funder(s)

Funder type

Research organisation

Funder Name

Network of Research on AIDS (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	01/02/2007		Yes	No