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

Submission date
20/10/2005

Registration date
08/11/2005

Last Edited
20/11/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary outcome measures
1. Virological, clinical and immunological efficacy
2. Tolerability

Overall study start date
15/01/2001

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
232 patients (116 per arm)

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)

Sponsor details
IDIBAPS
c/Villarroel 170

Barcelona
Spain
08036

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

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