ISRCTN24813210 https://doi.org/10.1186/ISRCTN24813210

Randomised, multicentre, open clinical trial assessing the effectiveness and safety of simplification to atazanavir + ritonavir versus continuation of a stable antiretroviral regimen on lopinavir/ritonavir

Submission date
12/09/2005

Registration date
20/01/2006

Last Edited
04/08/2009

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

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Additional identifiers

Protocol serial number
ATAZIP

Study information

Scientific Title

Study objectives
Comparison of the effectiveness and tolerability when switching lopinavir/ritonavir to atazanavir + ritonavir in HIV-1-infected patients on lopinavir/ritonavir and viral load <200 copies/ml.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised open-label controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic human immunodeficiency virus (HIV) infection.

Interventions
1. Continue current therapy
2. Switch lopinavir/ritonavir to atazanavir 300 mg + ritonavir 100 mg once a day (QD)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Atazanavir + ritonavir and lopinavir/ritonavir

Primary outcome(s)
Proportion of patients with two consecutive viral load determinations above 200 copies/ml (polymerase chain reaction [PCR] estándar, Amplicor Monitor Roche) during the study period (12 months after randomization).

Key secondary outcome(s))
1. Mean increase in CD4 counts
2. Incidence of adverse events (clinical and laboratory) leading to treatment discontinuation
3. Changes in lipid profile (cholesterol, triglyceride) and insulin resistance
4. Anthropometric changes
5. Incidence of C events (CDC 1993)
6. Death for any cause

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Male and female
2. HIV-1 infection
3. Age 18 and above
4. On antiretroviral therapy including lopinavir/ritonavir for at least 6 months
5. Viral load <200 copies/ml for at least 3 months
6. 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. Pregnancy, breastfeeding, intention to become pregnant during study period
2. Aspartate aminotransferase (ASAT) or alanine aminotransferase (ALAT) >/= 5 x upper limit of normal (ULN); creatinine >/= 2.0 mg/dl; total bilirubin >/= 3 x ULN
3. Alcoholism or drug abuse potentially impairing adherence or increasing risk of pancreatitis or hepatitis
4. Any formal contraindication to receive the study drugs
5. Active heart conduction alterations or long QTc or electrocardiogram (ECG) suggesting atrioventricular (AV) block
6. Patients with five or more mutations of resistance to protease inhibitors (PIs)
7. Patients with more than two virological failures to PIs

Date of first enrolment
15/02/2004

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Spain

Study participating centre
Infectious Diseases and HIV Unit
Barcelona
Spain
08036

Sponsor information

Organisation
Sponsor not yet defined (Spain)

Funder(s)

Funder type
Industry

Funder Name
Bristol-Myers Squibb (BMS)

Alternative Name(s)
Bristol-Myers Squibb Company, Bristol Myers Squibb, Bristol-Myers Company, BMS

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009		Yes	No