

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

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

20/01/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

04/08/2009

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

Dr Jose Gatell

Contact details

Infectious Diseases and HIV Unit
Hospital Clinic
Villarroel 170
Barcelona
Spain
08036

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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).

Secondary outcome measures

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

Overall study start date

15/02/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

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)

Sponsor details

Infectious Diseases and HIV Unit

Hospital Clinic

Villarroel 170

Barcelona

Spain

08036

Sponsor type

Not defined

Funder(s)

Funder type

Industry

Funder Name

Bristol-Myers Squibb (BMS)

Alternative Name(s)

Bristol-Myers Squibb Company, BMS

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

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	01/05/2009		Yes	No