

Comparison of two alternative combinations of nucleosides in HIV-1 infected patients with viral suppression on 3TC. Randomized, multicentre open trial.

Submission date 09/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/09/2012	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jose M Gatell

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

Additional identifiers

Protocol serial number
BICOMBO

Study information

Scientific Title

Study objectives

Compare virological response 48 weeks after switching the nucleoside analogue component.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic human immunodeficiency virus (HIV) infection.

Interventions

Switch nucleoside component of HAART to either Kivexa® or Truvada®.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

abacavir/lamivudine (Kivexa®) , tenofovir/emtricitabine (Truvada®)

Primary outcome(s)

Proportion of patients with undetectable viral load at 48 weeks.

Key secondary outcome(s)

1. Time to virological failure
2. Incidence of clinical and laboratory adverse events leading to treatment discontinuation
3. Incidence of C events (CDC, 1993)
4. Change in CD4 from baseline
5. Change in triglyceride, cholesterol (total and high density lipoprotein [HDL] and low density lipoprotein [LDL])
6. Mutations of resistance in failing patients

Completion date

30/06/2007

Eligibility

Key inclusion criteria

1. Male and female
2. HIV-1-infected
3. Age 18 and above
4. On stable highly active antiretroviral therapy (HAART), including lamivudine (3TC) for at least last 3 months
5. Plasma viral load <200 copies/ml for at least 4 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 or intent to become pregnant during the study period
2. Active opportunistic infection requiring treatment by parenteral route
3. Creatinine (serum) >2 mg/dl
4. Current treatment with potentially nephrotoxic agents: aminoglycosides, amfotericin B, cidofovir, cisplatin, foscarnet, pentamidine IV
5. Treatment with adefovir, probenecid, interleukin-2, systemic steroids or investigational agents
6. Systemic antineoplastic chemotherapy
7. Any contraindication for study drugs
8. Prior failure on combinations including abacavir or tenofovir or with mutations of resistance to these drugs

Date of first enrolment

01/07/2005

Date of final enrolment

30/06/2007

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

Gilead Sciences

Alternative Name(s)

Gilead, Gilead Sciences, Inc., Oligogen

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

GlaxoSmithKline (GSK)

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

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	01/07/2009		Yes	No
Results article	substudy results on body composition	01/07/2012		Yes	No