ISRCTN61891868 https://doi.org/10.1186/ISRCTN61891868

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

Registration date
20/01/2006

Overall study status
Completed

Last Edited
07/09/2012

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
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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: aminoglicosides, 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