

Evaluation of two Trizivir-based strategies of induction-maintenance in antiretroviral-naive HIV-infected patients

Submission date
12/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
19/01/2006

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
24/07/2014

Condition category
Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

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
+34 (0)932275430
gatell@medicina.ub.es

Additional identifiers

Protocol serial number

TRIZEFAL

Study information

Scientific Title

Study objectives

To assess the virological and immunological response in naive patients undergoing induction (24 weeks of intensive therapy with three nucleoside reverse transcriptase inhibitors [NRTIs] plus either a protease inhibitor or a non-nucleoside) followed by 48 weeks of maintenance therapy with three NRTIs.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Human immunodeficiency virus (HIV) infection

Interventions

Patients are randomly assigned to receive either:

1. Retrovir (AZT) + Lamivudine (3TC) + Trizivir (ABC) + Efavirenz (Sustiva), or
2. AZT + 3TC + ABC + Lopinavir/Ritonavir (Kaletra)

After 24 weeks, patients in both arms showing undetectable viral load will receive Trizivir for 48 more weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Trizivir (ABC), Lamivudine (3TC), Retrovir (AZT), Efavirenz (Sustiva), Lopinavir/ritonavir (Kaletra)

Primary outcome(s)

Proportion of patients with viral load below 20 copies/ml (polymerase chain reaction [PCR] estandar, Amplicor Monitor Roche Ultrasensible) at 72 weeks.

Key secondary outcome(s)

1. Proportion of patients with CD4+ cell count above 200 c/ml at 72 weeks
2. Proportion of patients with viral load <20 copies/ml at 24 weeks

3. Time to treatment failure
4. Duration of response
5. Incidence of adverse events (clinical and laboratory) leading to discontinuation of the study drugs
6. Incidence of C events (CDC 1993)
7. Death for any cause

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Male and female
2. HIV-1 infection
3. Age 18 or above
4. Antiretroviral-naïve
5. Plasma viral load above 10,000 copies/ml
6. Life expectancy >72 weeks
7. 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 intention to become pregnant during the study planned duration
2. Current opportunistic infection requiring parenteral therapy
3. Any formal contraindication to receive the study drugs
4. Current treatment with investigational drugs

Date of first enrolment

15/04/2003

Date of final enrolment

31/12/2005

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

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

