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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/01/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/07/2014	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
15/04/2003

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Male and female
2. HIV-1 infection
3. Age 18 or above
4. Antiretroviral-naive
5. Plasma viral load above 10,000 copies/ml
6. Life expectancy >72 weeks
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

220

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)

Sponsor details
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Sponsor type
Not defined

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (GSK)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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