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Prospective, multi-center, one-arm pilot trial of Trizivir plus Tenofovir in adult HIV-infected antiretroviral-naive patients

Submission date	Recruitment status	[_] Prospectively registered
14/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2020	Infections and Infestations	

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
TTstudy-04

Study information

Scientific Title
Prospective, multi-center, one-arm pilot trial of Trizivir plus Tenofovir in adult HIV-infected antiretroviral-naive patients

Acronym
TT

Study objectives
A combination of trizivir plus tenofovir will be associated with a good efficacy and tolerability in antiretroviral naive patients, even in those with high baseline viral loads and low CD4 counts.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Local ethical committee, approved on November 10, 2004
2. National Health Authorities (Agencia Española del Medicamento), approved on November 18, 2004

Study design
Prospective, multi-center, one-arm pilot trial.

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
HIV infection

Interventions
All participants will initiate an antiretroviral regimen of Trizivir® (Active ingredients: zidovudine 300 mg + lamivudine 150 mg + abacavir 300 mg) 1 pill orally twice a day (bid) plus tenofovir 300 mg orally everyday (qd). The duration of the intervention is 2 years prolonged to a third if efficacy and tolerability are acceptable.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Viral load <50 copies/mL. Viral load is measured at baseline, week 2, 4, 12 and every 12 weeks thereafter up to the end of the study period.

Secondary outcome measures
1. CD4 changes, measured at baseline, week 12 and every 12 weeks thereafter up to the end of the study period.
2. Adverse effects. Clinical signs related to adverse effects are evaluated every 3 months
3. Resistance mutations if virologic failure
4. Clinical progression, evaluated every 3 months
5. Adherence to therapy, evaluated every 3 months

Overall study start date
13/12/2004

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Confirmed HIV infection
2. Age >= 18 years
3. AntiRetroViral (ARV) naive
4. CD4 > 100 cells/uL
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
93

Key exclusion criteria
1. Alanine aminotransferase >5 Upper Limit of Normal (ULN)
2. Hepatic cirrhosis
3. Renal insufficiency with creatinine clearance <50 ml/min
4. Haemoglobin (Hb) <9 g/dL
5. Neutrophils <1,000/uL
6. Platelets <30,000/uL
7. Pregnancy
8. Acute infection in the last two weeks
9. Systemic treatment for neoplasms
10. Hepatitis C Virus+ (HCV+) in patients who require treatment with interferon/ribavirin

Date of first enrolment
13/12/2004

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Spain

Study participating centre
Infectious Disease Service
Barcelona
Spain
08907

Sponsor information

Organisation
Institute of Biomedical Investigations of Bellvitge (Institut d'Investigació Biomèdica de Bellvitge) (IDIBELL) (Spain)

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Sponsor type

Research organisation

Website
http://www.idibell.es

ROR
https://ror.org/0008xqs48

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Biomedical Investigations of Bellvitge (Institut d'Investigació Biomèdica de Bellvitge) (IDIBELL) (Spain)

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	01/07/2008	23/10/2020	Yes	No