

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

TTstudy-04

Study information

Scientific Title

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

Acronym

TT

Study objectives

A combination of trizivir plus tenofovir will be associated with a good efficacy and tolerability in antiretroviral naïve 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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

Completion date

30/06/2008

Eligibility

Key inclusion criteria

1. Confirmed HIV infection
2. Age $\geq$ 18 years
3. AntiRetroViral (ARV) naive
4. CD4 > 100 cells/uL
5. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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