

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

<b>Submission date</b> 14/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/10/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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-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

## 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  $\geq$  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)

**Sponsor details**

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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?
<a href="#">Results article</a>	results	01/07/2008	23/10/2020	Yes	No