# Effectiveness and Safety of Tenofovir + Lamivudine + Efavirenz Generic Scheme for the Treatment of HIV Infection / AIDS in Patients of the CLS,Colombia, 2012-2013.

---------- Public Title:
Effectiveness and Safety of Tenofovir + Lamivudine + Efavirenz Generic Scheme for the Treatment of HIV Infection / AIDS in Patients of the CLS,Colombia, 2012-2013.
---------- Scientific Title:
Effectiveness and safety of tenofovir + lamivudine + efavirenz generic scheme for the treatment of HIV infection / AIDS in patients of the Corporacion de lucha contra el Sida, Santiago de Cali-Colombia, 2012-2013.
---------- Secondary Identifying Numbers:
UTN: U1111-1130-8685
---------- Issuing Authority of the Secondary Identifying Numbers:
---------- Primary Sponsor:
Corporación de Lucha Contra el Sida
---------- Secondary Sponsor(s):
HUMAX FARMACÉUTICA.
---------- Source(s) of Monetary or Material Support:
Corporación de Lucha Contra el Sida
HUMAX FARMACÉUTICA.
---------- Regulatory authority to approve the initiation to the study:
Only approved by Ethics Committees
---------- Authorization Date:
---------- Reference Number:
---------- Countries of Recruitment:
Colombia
---------- Province of Principal Site:
Valle del Cauca
---------- Principal Clinical Site:
Corporación de Lucha Contra el Sida
---------- Principal Investigator:
Jaime Galindo Quintero, MD. Specialist of Internal medicine
---------- Other Clinical Sites:
Not applicable
---------- Research Ethics Committees:
Corporación de Lucha Contra el Sida, 18 de abril de 2012 (IRB00005732 - Act 024)
---------- Recruitment Status:
1. Pending
---------- Date of First Enrollment:
23/07/2012 20:00
---------- Health Condition(s) or Problem(s) Studied.:
HIV/AIDS
---------- Intervention(s):
Generic scheme of treatment in Study: Tenofovir 300 mg (1 tablet daily) + lamivudine 150 mg (2 tablets a day) + Efavirenz 600 mg (1 tablet per day).

This treatment will apply to two groups of patients:
Group 1 (n1=40). Patients diagnosed as HIV+ by laboratory test and clinical findings who need antiretroviral treatment and have not yet started
Group 2 (n2=40). Patients who need optimized antiretroviral treatment
---------- Primary Outcome(s):
Virological status (viral load). Measurement time: at baseline, 3, 6, 12 months of treatment.
Immunological status (CD4+ cell count). Measurement time: at baseline, 3, 6, 12 months of treatment.
Frequency of adverse reactions to antiretrovirals (Description of the reactions, the severity of the reaction and its possible association with antiretroviral drugs, most convenient solution (symptomatic, adjustment of medication schedules, interruption and / or replacement of treatment)). Measurement time: at baseline,, 3, 6, 12 months of treatment
---------- Key Secondary Outcomes:
Liver test (Transaminases). Measurement time: at baseline, 3, 6, 12 months of treatment.
Renal test (Creatinine, Urinalysis, Calciuria, phosphate. If phosphatemia and calciuria are abnormal, then the bone densitometry will be done). Measurement time: at baseline, 3, 6, 12 months of treatment.
Hematologic test (Complete blood count: hemoglobin, hematocrit, corpuscular volume, total leukocyte and neutrophil differential cell count, platelet count). Measurement time: at baseline, 3, 6, 12 months of treatment.
Metabolic function test and anthropometric measurements (glucose, total cholesterol, HDL, LDL, blood pressure index, triglycerides, weight in kilograms, height in centimeters, body mass index, blood pressure, waist circumference). Measurement time: at baseline, 3, 6, 12 months of treatment.
---------- Gender:
3. Both
---------- Minimun Age:
18 years
---------- Maximun Age:
65 years
---------- Inclusion Criteria:
1) Outpatient adults (> 18 years), who agree to participate through informed consent, in the Program for Comprehensive Care Specialized Ambulatory of Corporación de Lucha contra el Sida diagnosed as HIV +, by laboratory testing (presumptive tests and confirmatory test, count of CD4 cells and percentage by flow cytometry and viral load values by virus copies/mL with PCR assay in reverse transcriptase real-time.
2) With the result of negative resistance genotypic study (analyzed and interpreted under the most current recommendations for the management of HIV infection in the world), and/or without clinical/epidemiological evidence of any possible effects of the susceptibility of the drugs under study.
3) Patients without past or present renal disease
4) Patients without prior exposure to ARVs, with contraindications to the use of AZT and / or ABC within their first ARV regimen, or with previous exposure to ARV "first line" (2 NRTIs + 1 NNRTI) successful (maximum constant viral suppression), without therapeutic failure but with the appearance of a side or undesirable effects attributable(s) primarily to NRTIs used (such as severe gastrointestinal intolerance, blood disorders, lipid and cardiovascular risk changes, lipoatrophy, lactic acidosis, risk or occurrence of hypersensitivity reactions, etc.).
5) That clinically and by guides(2011-2012) of the Corporación de Lucha contra el Sida and supported by the latest recommendations for the initiation of such treatment in the world that they are willing to comply with this ARV treatment and they don't start it o receive previously.
---------- Exclusión criteria:
1) Patients with renal failure (serum creatinine equivalent to an estimated creatinine clearance less than 60 mL/ minute). Patients with serum creatinine greater than 1.5 mg%.
2) Patients with liver failure associated with primary or other disease.
3) women who are pregnant or lactating, or of childbearing age without contraception permanent or safer method.
4) Patients who are using drugs or require a high probability of clinically relevant interactions (such as Rifampicin, Itraconazole, etc.).

5) Patients hospitalized.
6) Patients with major psychiatric disorders.
7) Patients with a history and / or substance abuse problems not intervened.
8) Patients with variable work schedules that include night shifts.
---------- Type of Participant:
2. Patients
---------- Type of study:
1. Interventional
---------- Allocation:
2. Nonrandomized Trial
---------- Masking:
1. Open.
---------- Control Group:
2. Active
---------- Study Design:
2. Parallel
---------- Other Design:
---------- Purpose:
1. Treatment
---------- Phase:
8. Phase IV
---------- Target Sample Size:
80
---------- First Name (Contact for Public Queries):
Jaime
---------- Middle Name (Contact for Public Queries):
---------- Last Name (Contact for Public Queries):
Galindo-Quintero
---------- Affiliation (Contact for Public Queries):
Corporación de Lucha Contra el Sida
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jaimegalindo@cls.org.co
---------- Primary Register:
RPCEC
---------- Unique ID number:
RPCEC00000134
---------- Date of Registration in Primary Register:
20/07/2012 20:00
---------- Record Verification Date:
18/07/2012 20:00
Next Update Date:
18/07/2013 20:00
DIRECTIONS: Please, fill the data distributed in tabs. Use the “Next” and “Previous” buttons to switch tabs and the “Save” button to store form data. Click in the “Next” button to begin filling the form.:

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