

New study measures HIV anti-retroviral regimens' safety and efficacy

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Eric Daar, M.D., is LA BioMed's principal investigator on a study comparing safety and effectiveness of anti-retroviral regimens in treatment of HIV. Credit: LA BioMed

A study in the *New England Journal of Medicine* released on World AIDS Day reports that viral failure, the point at which medication can no longer suppress the HIV infection, was twice as likely and happened sooner among patients initiating anti-retroviral therapy with high viral loads who were given Epzicom when compared to similar patients treated with Truvada.

The research team was led by several investigators including Eric Daar,

MD, a principal investigator at Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center (LA BioMed), and it enrolled 1,858 patients in a study conducted through the [AIDS Clinical Trials](#) Group. The study, A5202, examined the safety and efficacy of four once-daily anti-retroviral regimens as initial therapy for HIV-1 infection.

Among the 797 patients initiating therapy with higher viral loads (100,000 copies per milliliter or more), the researchers found that those given Epzicom (a combination of abacavir and lamivudine) had twice as many virologic failures as those given Truvada (a combination of tenofovir DF and emtricitabine) after a median of 60 weeks of treatment.

The significant difference in effectiveness led the data and safety monitoring board of the National Institute of Allergy and Infectious Diseases to halt the portion of the study comparing Truvada to Epzicom in those with higher viral loads in 2008, nearly two years earlier than planned. The researchers continued to follow the patients' medical progress in order to address several other scientific questions being studied in A5202.

"The patients in the study all did quite well. But for those starting with high viral loads, there was a highly significant difference in outcomes that favored those given Truvada compared to Epzicom," said Dr. Daar. "As we mark World's AIDS Day this year, we can celebrate the fact that there are many effective therapeutic options for the treatment of HIV-infected individuals and much ongoing research, like this study, to further refine and optimize the management of this disease."

World AIDS Day has been held on Dec. 1 of every year since 1988 to raise awareness around the world about AIDS and [HIV](#). The study released by NEJM on World AIDS Day 2009 reports on research in which patients were randomly assigned to receive one of four oral once-

daily regimens. Those regimens included Epzicom or Truvada with either Sustiva (efavirenz) or Reyataz (atazanavir) plus Norvir (ritonavir).

The researchers checked on the patients' medical conditions at 4, 8, 16 and 24 weeks after they entered the trial - then every 12 weeks thereafter for the duration of the study. Among the research volunteers who initiated therapy with high viral loads, viral failure occurred in 57 patients receiving Epzicom and in 26 patients taking Truvada. The group of patients taking Epzicom also had a significantly shorter time to virologic failure and adverse events than did patients who received Truvada.

The researchers will continue to examine the relative safety and effectiveness of Epzicom and Truvada in those starting therapy with lower viral loads and for the two other medications in the study, Sustiva and the Reyataz with Novir combination.

"This study and others like it help guide physicians and their patients in determining the optimal therapy for each individual with the goal of providing the safest and most effective regimens possible," said Dr. Daar.

More information: The study, entitled "Abacavir-Lamivudine versus Tenofovir-Emtricitabine for Initial HIV-1 Therapy," appears in the Dec. 3, 2009 issue of *NEJM*.

Source: UCLA Medical Center

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