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Tenofovir DF, Emtricitabine, and Efavirenz vs. Zidovudine, Lamivudine, and Efavirenz for HIV

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ABSTRACT

Background Durable suppression of replication of the human immunodeficiency virus (HIV) depends on the use of potent, well-tolerated antiretroviral regimens to which patients can easily adhere.

Methods We conducted an open-label, noninferiority study involving 517 patients with HIV infection who had not previously received antiretroviral therapy and who were randomly assigned to receive either a regimen of tenofovir disoproxil fumarate (DF), emtricitabine, and efavirenz once daily (tenofovir–emtricitabine group) or a regimen of fixed-dose zidovudine and lamivudine twice daily plus efavirenz once daily (zidovudine–lamivudine group). The primary end point was the proportion of patients without baseline resistance to efavirenz in whom the HIV RNA level was less than 400 copies per milliliter at week 48 of the study.

Results Through week 48, significantly more patients in the tenofovir–emtricitabine group reached and maintained the primary end point of less than 400 copies of HIV RNA per milliliter than did

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those in the zidovudine–lamivudine group (84 percent vs. 73 percent, respectively; 95 percent confidence interval for the difference, 4 to 19 percent; P=0.002). This difference excludes the inferiority of the tenofovir DF, emtricitabine, and efavirenz regimen, indicating a significantly greater response with this regimen. Significant differences were also seen in the proportion of patients with HIV RNA levels of less than 50 copies per milliliter (80 percent in the tenofovir–emtricitabine group vs. 70 percent in the zidovudine–lamivudine group; 95 percent confidence interval for the difference, 2 to 17 percent; P=0.02) and in increases in CD4 cell counts (190 vs. 158 cells per cubic millimeter, respectively; 95 percent confidence interval for the difference, 9 to 55; P=0.002). More patients in the zidovudine–lamivudine group than in the tenofovir–emtricitabine group had adverse events resulting in discontinuation of the study drugs (9 percent vs. 4 percent, respectively; P=0.02). In none of the patients did the K65R mutation develop.

Conclusions Through week 48, the combination of tenofovir DF and emtricitabine plus efavirenz fulfilled the criteria for noninferiority to a fixed dose of zidovudine and lamivudine plus efavirenz and proved superior in terms of virologic suppression, CD4 response, and adverse events resulting in discontinuation of the study drugs. (ClinicalTrials.gov number, NCT00112047 [ClinicalTrials.gov] .)

Source Information

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- (2006). What's the Optimal Initial ART Regimen for HIV?. *Journal Watch Infectious Diseases* 2006: 2-2 [Full Text]
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