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Clinical Science

Randomized, double-blind, placebo-matched, multicenter trial of abacavir/lamivudine or tenofovir/emtricitabine with lopinavir/ritonavir for initial HIV treatment

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Abstract

Background: Abacavir sulfate/lamivudine (ABC/3TC) and tenofovir DF/emtricitabine (TDF/FTC) are widely used nucleoside reverse transcriptase inhibitors for initial HIV-1 treatment. This is the first completed, randomized clinical trial to directly compare the efficacy, safety, and tolerability of these agents, each in combination with lopinavir/ritonavir in antiretroviral-naïve patients.

Methods: Six hundred and eighty-eight antiretroviral-naïve, HIV-1-infected patients were randomized in this double-blind, placebo-matched, multicenter, noninferiority study to receive a once-daily regimen of either ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg, both with lopinavir/ritonavir 800 mg/200 mg. Primary endpoints were the proportion of patients with HIV-1 RNA below 50 copies/ml at week 48 (missing = failure, switch included analysis) and the proportion of patients experiencing adverse events over 96 weeks.

Results: At week 48, 68% in the ABC/3TC group vs. 67% in the TDF/FTC group achieved an HIV-1 RNA below 50 copies/ml (intent-to-treat exposed missing = failure, 95% confidence interval on the difference -6.63 to 7.40, $P = 0.913$), demonstrating the noninferiority of ABC/3TC to TDF/FTC at week 48. Noninferiority of the two regimens was sustained at week 96 (60% vs. 58%, respectively, 95% confidence interval -5.41 to 9.32, $P = 0.603$). In addition, efficacy of both regimens was similar in patients with baseline HIV-1 RNA $\geq 100\ 000$ copies/ml or CD4⁺ cell counts below 50 cells/ μ l. Median CD4⁺ recovery (ABC/3TC vs. TDF/FTC, cells/ μ l) was +250 vs. +247 by week 96. Premature study discontinuation due to adverse events occurred in 6% of patients in both groups. Protocol-defined virologic failure occurred in 14% of patients in both groups.

Conclusion: Both ABC/3TC and TDF/FTC provided comparable antiviral efficacy, safety, and tolerability when each was combined with lopinavir/ritonavir in treatment-naïve patients.

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