COMPARISON OF THAI GOVERNMENT MANUFACTURED TENOFOVIR (TENOFOVIR GPO300) WITH PRIVATELY MANUFACTURED TENOFOVIR (VIREAD) USED ALONG WITH LAMIVUDINE AND EFAVIRENZ TO TREAT THAI HIV PATIENTS

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Abstract. The Thai Government Pharmaceutical Organization (GPO) has produced a nucleotide reverse transcriptase inhibitor, tenofovir disoproxil fumarate (Tenofovir GPO300). No clinical trial to date has compared plasma tenofovir concentrations, renal function, and treatment responses in HIV-infected patients who received Tenofovir GPO300 versus Viread (original tenofovir) as part of an antiretroviral regimen. We studied 129 antiretroviral treatment (ART)-naive HIV-1 infected patients who received an antiretroviral regimen of lamivudine, efavirenz and Tenofovir GPO300 (n=65) or Viread (n=64). We examined plasma tenofovir concentrations (12 hours after dosing), serum creatinine, estimated glomerular filtration rate (eGFR) using the Modification in Diet in Renal Disease (MDRD) study formula, fractional excretion of phosphate (FEphos), CD4 and plasma HIV-1 RNA levels at 12 weeks, and CD4 and plasma HIV-1 RNA levels at 24 weeks after initiating the drugs. At baseline, the mean±SD subject body weight was 54±10 kilograms and the mean±SD subject age was 37±8 years. At baseline, the median (IQR) CD4 count was 44 (18-120) cells/mm³ and the median (IQR) HIV-1 RNA level was 5.8 log copies/ml. At baseline, the mean±SD eGFR was 134.8±43.6 ml/min/1.73 m². The baseline values for the two groups were not significantly different from each other (p>0.05). At 12 weeks, the mean±SD plasma tenofovir concentration was 106.9±41.5 ng/ml among the patients who received Tenofovir GPO300 and 100.7±49.4 ng/ml among those who received Viread (p=0.437). At week 12, there were no differences between those who received Tenofovir GPO300 and Viread in mean serum creatinine (0.78 vs 0.81 mg/dl, p=0.283), mean eGFR (117.9 vs 109.1 ml/min/1.73 m², p=0.089), decline in eGFR from baseline (-21.8 vs -20.6 ml/min/1.73 m², p=0.860) or mean FEphos (11.4 vs 11.2, p=0.923). The median CD4 cell counts and number of patients with undetectable plasma HIV-1 RNA at week 24 were not significantly different (p>0.05) between those who took Tenofovir GPO300 and Viread. In summary, plasma tenofovir concentrations, changes in renal function, urinary phosphate excretion and treatment responses were comparable between HIV-infected patients who received Tenofovir GPO300 and Viread-containing non-nucleoside reverse transcriptase regimens.

Keywords: Tenofovir GPO300, tenofovir, HIV, Thailand

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