TITLE: Therapeutic drug monitoring safety and efficacy of the generic Lopinavir/Ritonavir tablets 200/50 mg in Thai HIV-infected patient

ชื่อภาษาไทย: -

AUTHOR ศ.นพ.เกียรติ รักษ์รุ่งธรรม
ศูนย์วิจัยโรคเอดส์ สภากาชาดไทย

ABSTRACT

Background: Generic products in HIV-care can considerably reduce the costs. However, very few generic second line antiretroviral products are available. Generic lopinavir/ritonavir produced by the Government Pharmaceutical Organization, Thailand, was tested in Thai HIV infected adults in order to improve the access to high quality generic products.

Methods: Seventy patients were enrolled in this single arm prospective study. Patients could either be protease inhibitor (PI) naïve or on a PI-containing regimen for at least 24 weeks before entering the study, with no evidence of PI failure (HIV RNA < 50 copies/mL). Patients were started on generic LPV/r tablets, 400/100 mg twice daily (BID). At week 4, after steady state has been reached, therapeutic drug monitoring was performed and analyzed by a validated high-performance liquid chromatography (HPLC) method. In patients on Kaletra soft gel capsules (SGC), TDM was performed at baseline to compare with the generic GPO product.

Results: 38 males and 32 females were enrolled. The mean (SD) age was 40.7 (7.9) years and the mean (SD) body weight was 60.3 (9.0) kg. The mean (SD) minimal concentration (C_{min}) of LPV at week 4 was 7.1 (2.9) mg/L and of RTV was 0.39 (0.21) mg/L. In 22 patients who were on the Kaletra SGC before study entry, the C_{min} while on Kaletra was not significantly different from the C_{min} while on the generic GPO product. The found LPV C_{min} was also comparable to the previously found LPV C_{min} of the generic Matrix product. After 48 weeks, 95.6% of patient had HIV-RNA <50 copies/mL and 100% of patients had HIV-RNA <400 copies/mL.

Conclusions: Generic LPV/r in the standard dose of 400/100 mg BID showed adequate levels and good tolerability. The 48 week efficacy was excellent.