

Immunologic and virologic responses to generic highly active antiretroviral therapy of patients with single dose nevirapine or short course AZT pre-exposure, in Zimbabwe.

Lynn S. Zijenah¹, G. Kadzirange², O. Tobaiwa¹, T. Kufa³, E. Matsikire⁴, S. Moyo⁴, D. Bhattacharaya⁵, C. Maponga⁶, N. Gonah², ZM. Chirenje⁷, DA. Katzenstein⁵

University of Zimbabwe College of Health Sciences, Departments of Immunology¹, Community Medicine⁴, Pharmacy⁶ and Obstetrics and Gynaecology⁷, Harare, Zimbabwe, Chitungwiza Municipality², Chitungwiza, Zimbabwe, MSF³, Barcelona, Spain and Stanford University⁵, Stanford, California, USA.

Background: Generic antiretroviral drugs for treatment of AIDS as well as single dose (SD) nevirapine (NVP) or short course (SC) AZT for reducing mother to child transmission of HIV are becoming increasingly available in developing countries. The efficacy of an NVP-containing triple regimen for treatment of AIDS in SD NVP pre-exposed patients is of major interest.

Objective: To evaluate immunologic and virologic responses to generic highly active antiretroviral therapy (HAART) in patients with SC AZT or SD NVP pre-exposure.

Methods: Women and their partners with SC AZT or SD NVP pre-exposure and CD4⁺ cells <200 were initially offered cotrimoxazole then, HAART comprising “duovir” (generic AZT/lamivudine) and “nevimune” (generic NVP), from CIPLA, India. Laboratory tests at baseline and week 16 included complete blood count, urea and electrolytes, ALT, CD4 counts and virus load. Drugs were dispersed weekly for the first month, then monthly thereafter. Nurses and community lay counselors monitored adherence.

Results: Fifty-two patients initiated HAART between July and October 2003, 29 patients (15 women and 14 men) reached week 16 by December 2003; 23 and 6 pre-exposed to SC AZT and SD NVP respectively. Mean CD4 count for females and males was 101.9 ± 47.0 and 101.5 ± 52.6 cells / μ L respectively, with a geometric mean virus load of $\log_{10} 5.0$. Adherence was >95%. At week 16, 89% of the patients had undetectable virus ($<\log_{10} 2.6$), mean CD4 count for females and males increased to 227.9 ± 92.1 and 214.6 ± 96.7 cells/ μ L respectively. Two discordant responders with undetectable virus at week 16 but unchanged CD4 counts from baseline were identified.

Conclusion: Generic HAART, substantially increased CD4 counts and decreased virus load by week 16. Pre-exposure to SC or SD monotherapy does not appear to influence response to HAART. HAART success may be attributable to high drug adherence by the patients, achieved through community involvement.