

Characteristics of HIV-1 Serodiscordant Couples Enrolled in a Clinical Trial of Antiretroviral Pre-Exposure Prophylaxis for HIV-1 Prevention

Abstract:

Introduction Stable heterosexual HIV-1 serodiscordant couples in Africa have high HIV-1 transmission rates and are a critical population for evaluation of new HIV-1 prevention strategies. The Partners PrEP Study is a randomized, double-blind, placebo-controlled trial of tenofovir and emtricitabine-tenofovir pre-exposure prophylaxis to decrease HIV-1 acquisition within heterosexual HIV-1 serodiscordant couples. We describe the trial design and characteristics of the study cohort. **Methods** HIV-1 serodiscordant couples, in which the HIV-1 infected partner did not meet national guidelines for initiation of antiretroviral therapy, were enrolled at 9 research sites in Kenya and Uganda. The HIV-1 susceptible partner was randomized to daily oral tenofovir, emtricitabine-tenofovir, or matching placebo with monthly follow-up for 24–36 months. **Results** From July 2008 to November 2010, 7920 HIV-1 serodiscordant couples were screened and 4758 enrolled. For 62% (2966/4758) of enrolled couples, the HIV-1 susceptible partner was male. Median age was 33 years for HIV-1 susceptible and HIV-1 infected partners [IQR (28–40) and (26–39) respectively]. Most couples (98%) were married, with a median duration of partnership of 7.0 years (IQR 3.0–14.0) and recent knowledge of their serodiscordant status [median 0.4 years (IQR 0.1–2.0)]. During the month prior to enrollment, couples reported a median of 4 sex acts (IQR 2–8); 27% reported unprotected sex and 14% of male and 1% of female HIV-1 susceptible partners reported sex with outside partners. Among HIV-1 infected partners, the median plasma HIV-1 level was 3.94 log₁₀ copies/mL (IQR 3.31–4.53) and median CD4 count was 496 cells/μL (IQR 375–662); the majority (64%) had WHO stage 1 HIV-1 disease. **Conclusions** Couples at high risk of HIV-1 transmission were rapidly recruited into the Partners PrEP Study, the largest efficacy trial of oral PrEP. (ClinicalTrials.gov NCT00557245).