

Antiretroviral Drugs Protect Against HIV-1 Infection in Heterosexuals

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In a result that will fundamentally change approaches to HIV prevention in Africa, an international study has demonstrated that individuals at high risk for HIV infection who took a daily tablet containing an HIV medication – either the antiretroviral medication tenofovir (TDF) or tenofovir in combination with emtricitabine (FTC/TDF) – experienced significantly fewer HIV infections than those who received a placebo pill. These findings are clear evidence that this new HIV prevention strategy, called pre-exposure prophylaxis (or PrEP), substantially reduces HIV infection risk.

The study was led by University of Washington's Dr. Jared Baeten and Dr Connie Celum and Vaccine and Infectious Disease Division's Dr. Deborah Donnell, along with collaborators in the Partners Pre-exposure Prophylaxis (PrEP) Study and enrolled 4758 heterosexual serodiscordant couples from nine sites in Kenya and Uganda. Seronegative partners were assigned to one of three study groups: TDF, TDF-FTC, or placebo. The seropositive partner, at study enrollment, was not eligible for antiretroviral therapy according to national guidelines. Couples were in the study for up to three years; seronegative participants had monthly visits for HIV-1 testing, dispensation of study medication, and other HIV-1 prevention services and counseling.

During the study, a total of 82 HIV-1 infections occurred in seronegative participants: 17 in the TDF group (incidence, 0.65 per 100 person-years), 13 in the TDF-FTC group (incidence, 0.50 per 100 person-years), and 52 in the placebo group (incidence, 1.99 per 100 person-years). This represents a relative reduction in risk of HIV-1 infection of 67% with TDF and 75% with FTC/TDF. The protective effects of the two preexposure prophylaxis treatments were not significantly different from each other, and both TDF and FTC/TDF significantly reduced HIV-1 incidence in both men and women. This study demonstrates that preexposure prophylaxis could be an effective HIV-1 prevention strategy for uninfected persons with partners who do not know their HIV status or are known to be infected, but have not yet become eligible for antiretroviral therapy. The researchers note that successful prevention of HIV-1 on a worldwide scale will likely need to incorporate multiple strategies, both medical and behavioral, to achieve maximum benefit and stem the global HIV-1 epidemic.

[Baeten JM, Donnell D, Ndase P, Mugo NR, Campbell JD, et al. 2012. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med*. Aug 2;367\(5\):399-410](#)

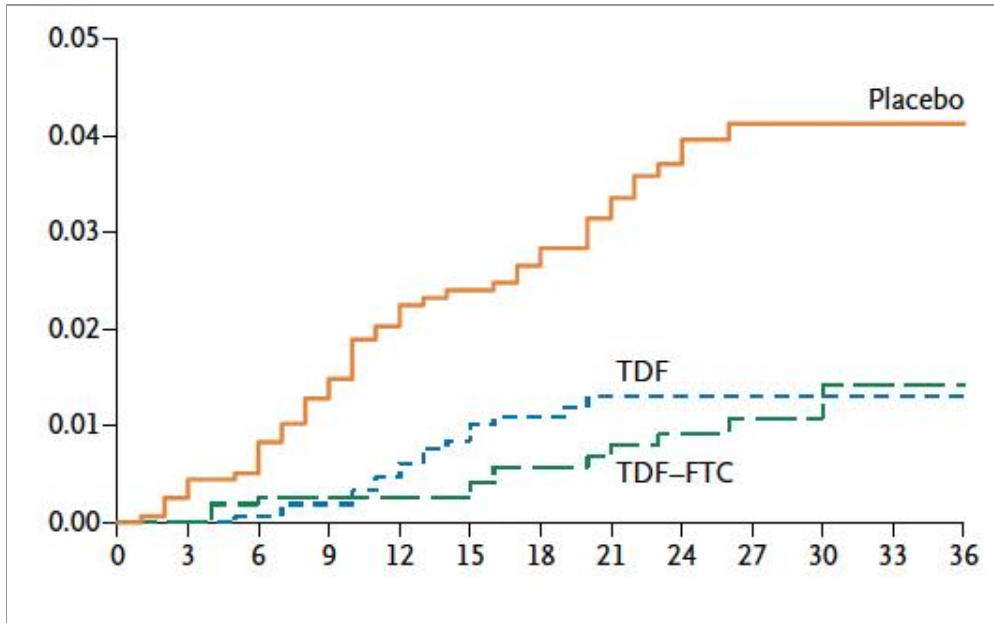


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Kaplan-Meier estimates of seropositivity in the modified intention-to-treat analysis, according to study treatment. Cumulative probability of HIV-1 infection is shown on the y-axis, and months since randomization is shown on the x-axis.