Study Finds PrEP Is Safe in Gay and Bi Men

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Pre-exposure prophylaxis (PrEP) with tenofovir (found in Viread, Truvada and Atripla) is safe for men who have sex with men (MSM), according to a U.S. study presented Friday, July 23, at the XVIII International AIDS Conference (IAC) in Vienna.

PrEP is one of the most promising prevention tools on the immediate horizon. With PrEP, HIV-negative individuals take antiretroviral drugs to prevent becoming infected with the virus. The first PrEP studies are testing tenofovir alone (Viread), while several later studies are testing tenofovir plus emtricitabine (Truvada). Currently, all studies are looking at daily ongoing use of the drugs, but future trials are planned with intermittent dosing. The first efficacy results are expected later this year, but researchers from the Centers for Disease Control and Prevention (CDC) in Atlanta presented findings from a safety study at this year's IAC.

For that study, CDC-4323, Lisa Grohskopf, MD, from the CDC and her colleagues enrolled 400 HIV-negative MSM. All reported having had anal sex with a man at least once during the previous year. The men were recruited in Atlanta, San Francisco and Boston. The majority were white, while 15 percent were African American, 9 percent were Hispanic and 4 percent were Asian or Pacific Islanders. Ultimately, 373 completed the course of the study.

There were four arms of the study. Half of the men in the study began taking tenofovir or a placebo right away. The second half were followed without study drugs for nine months and then given tenofovir or a placebo. This helped the researchers better understand how a person's risk behavior might change after beginning to take PrEP. The study was not designed to determine whether tenofovir could prevent HIV transmission, only whether or not it was safe compared with a placebo. All of the men were tested for HIV regularly and received rigorous HIV prevention counseling and condoms throughout the study.

Grohskopf and her colleagues found that men taking tenofovir had no more side effects than men taking a placebo. Two side effects of primary concern have been kidney and bone problems, which has been found in a small number of people with HIV who have taken the drug as treatment. Grohskopf's team measured the men's creatinine clearance—a measure of kidney function—and did bone scans to detect any potential problems in that regard. The team found no additional kidney or bone problems in those taking tenofovir, compared with a placebo.

CDC-4323 was also designed to measure how the participants' HIV risk behavior changed during the study. Though data on this issue is still being analyzed, Grohskopf reported that a preliminary analysis found that taking PrEP did not appear to lead study participants to forgo condoms or take other HIV risks.

"We didn't find any increased risk of harm in medical terms, and on the behavioral side the preliminary work we've done also suggests there is no increased risk," Grohskopf told Reuters News.

Given the promising results from a large tenofovir microbicide study—with a 39 percent reduction in HIV transmissions in women who used the tenofovir gel—establishing the safety of oral tenofovir provides even more hope that this strategy could be employed if the efficacy studies are successful.

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