“Surprising and Disappointing” Results in a New Truvada PrEP Study for Women

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A clinical trial testing the HIV-prevention potential of Truvada (tenofovir plus emtricitabine) in HIV-negative African women has been stopped early because of concerns about effectiveness, according to an announcement by the trial sponsor, Family Health International (FHI). This result stands in stark contrast to another study reported in late 2010, which found that Truvada cut new HIV infections by at least 44 percent in men who have sex with men (MSM) and transgender women.

Truvada is an antiretroviral (ARV) drug currently approved to treat people living with HIV. Several years ago, scientists suggested that the drug’s HIV-fighting power could also be used as prevention. Early studies in monkeys suggested that if the drug were given to HIV-negative people every day, it might keep them from becoming infected with HIV. Subsequent small studies in people found that it was likely to be safe, and so larger studies were launched in MSMs, transgender women, heterosexual women and heterosexual men.

The first of the large efficacy studies, called iPrEx, was reported in the late fall of 2010. That study—largely based in South America—found that in 2,500 MSM and transgendered women, those randomized to receive Truvada were 44 percent less likely to become infected with HIV. In those who reported taking the pill at least 90 percent of the time, new infections were cut by 73 percent, and in a small subgroup whose blood levels were monitored, Truvada appeared to cut infections by more than 90 percent in those who had measurable levels of Truvada in their blood.

The new study, FEM-PrEP, enrolled 1,951 heterosexual HIV-negative women who were at high risk for contracting HIV. The study was carried out in Kenya, Tanzania and South Africa by FHI and African academic partners. Women were randomized to receive either daily Truvada or a placebo. During a planned interim check of the data, the study monitors found that there were an equal number of new HIV infections in both the Truvada and placebo groups, making it highly unlikely that the study could determine whether or not Truvada was effective.

FHI, in its release, calls this finding “surprising and disappointing,” given the promise of Truvada in previous studies. Researchers state that follow-up with the HIV-negative study participants will be conducted over the next few months, but then an in-depth analysis of the data will

occur—including Truvada blood-level monitoring data—to help understand the study's results. Though the women in the study reported taking 95 percent of their doses, blood-level monitoring in the iPrEx revealed that fewer than 50 percent of those study participants were actually taking the drug, despite their claims otherwise.

According to FHI, "There are a number of possible reasons for the study findings, including low adherence to study regimen, a true lack of effect of the product among women (versus men who have sex with men), or other factors still to be determined."

In fact, one especially surprising result—which also suggests poor adherence could be at least part of the explanation—is that women taking Truvada were also more likely to become pregnant, despite the use of hormonal contraceptives, than women taking a placebo. "That's both a surprising finding and one that we can't readily explain," Timothy Mastro, MD, from FHI, told *The New York Times*.

No study conducted in the past decade has ever suggested that tenofovir could interfere with the blood levels of hormonal contraceptives. The researchers will be looking very closely to determine the reason for the additional pregnancies in the Truvada group.

It will take time to understand exactly what happened in the FEM-PrEP study. In the meantime, said Mitchell Warren, the executive director of the AIDS Vaccine Advocacy Coalition in New York City, "[FEM-PrEP] must be seen as what it is—the closure of a single trial in a field that has generated exciting results in the recent past."

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