Long-Acting Cabotegravir Is an Effective PrEP Option for Women

Cabotegravir injections and daily Truvada pills are both highly effective, but some people may find it easier to use the long-acting regimen.

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Injections of long-acting cabotegravir administered by a health care provider every other month were more effective than once-daily Truvada for preventing HIV among cisgender women, according to study results presented this week at the virtual HIV Research for Prevention conference (HIVR4P). Cabotegravir injections and daily Truvada pills are both highly effective, but some women may find it easier to use the long-acting regimen.

These results are comparable to those of a parallel trial of men and transgender women who have sex with men. While daily Truvada is around 99% effective for gay and bisexual men when used regularly, some studies of cisgender women have seen lower levels of protection, likely related to inconsistent use. Experts have suggested that long-acting prevention methods may be particularly appealing to women.

Sinead Delany-Moretlwe, MBBCh, PhD, of the University of the Witwatersrand in South Africa, presented interim results from the HPTN 084 trial, which enrolled 3,224 sexually active cisgender women at risk for HIV in seven countries in sub-Saharan Africa.

Nearly 60% were under 25, an age group at high risk for HIV in southern Africa. Most did not live with a partner, more than half reported having two or more sex partners in the past month and a third had a primary partner who was either HIV-positive or did not know their status. They could not be pregnant or breastfeeding and agreed to use contraception.

Participants in this double-blind trial were randomly assigned to receive injections of cabotegravir—a new integrase inhibitor—plus daily placebo pills or daily Truvada (tenofovir disoproxil fumarate/emtricitabine) plus placebo injections. The injectable regimen started with an oral lead-in using a cabotegravir pill for five weeks to ensure tolerability. After that, injections were administered in the buttocks at a clinic every other month. People who wished to stop cabotegravir were offered Truvada for a year after the last injection.

Although the trial was scheduled to run for more than three years, it was stopped early in November 2020 after an interim analysis found that cabotegravir injections were more effective

than the daily pills. Researchers released top-line results at that time, and Delany-Moretlwe filled in additional details at HIVR4P.

Of the 40 women who acquired HIV, 36 were taking daily Truvada and just four were taking long-acting cabotegravir. Two of the women who contracted HIV in the cabotegravir group had not recently received an injection. The HIV incidence rate was 1.86 per 100 person-years in the Truvada group versus 0.2 per 100 person-years in the cabotegravir group, reflecting an 89% lower risk with the injectable regimen. While both PrEP methods were effective, cabotegravir was found to be statistically superior.

Most participants remained in the study, with around 90% completing their injection appointments over the course of follow-up. However, in a random subset of 375 Truvada recipients, just 60% had drug levels consistent with daily dosing at week 4, falling to only about 30% after a year, which could explain the higher effectiveness of the injectable regimen.

These results are consistent with those of HPTN 083, a companion trial that enrolled 4,490 cisgender men and trans women in six countries, including the United States. As previously reported, that study also showed that cabotegravir was statistically superior to Truvada. Of the 52 people who acquired HIV, 39 were taking daily Truvada and 13 were taking long-acting cabotegravir, indicating that the injections reduced the risk of infection by 66% compared with the daily pills. That study was halted ahead of scheduled in May 2020.

Both cabotegravir and Truvada were safe and well tolerated. The mostly common side effect was injection site reactions such as pain, swelling or redness; these were reported by about a third of cabotegravir recipients after the first injection but the rate declined over time. These reactions were mostly mild or moderate, and none of the women withdrew from the study for this reason. Of note, injection site reactions were reported less often in this study compared with HPTN 083.

Women taking cabotegravir experienced an immediate increase in body weight (about 0.9 pounds) after starting the injections. However, this was small relative to the weight gain in both groups over the course of the study (about 5.3 pounds per year in the cabotegravir arm and about 4.8 pounds per year in the Truvada arm). Weight gain is a growing concern among people using integrase inhibitors for HIV treatment.

Women in the cabotegravir group were slightly more likely to become pregnant during the study. Among those who did, no additional adverse events were reported and none of their infants had congenital abnormalities.

Rates of sexually transmitted infections (STIs) were similar in both groups, indicating that the women in the two groups were at equal risk of acquiring HIV through sex.

Although long-acting cabotegravir requires a clinic visit for administration every other month, HIV and STI testing are recommended at least every three months for people taking Truvada, so the number of annual visits is not that much higher.

What’s more, Delany-Moretlwe noted at a press briefing in advance of the conference, many women are accustomed to receiving long-acting injectable contraception, and integrating long-acting PrEP would be a way to offer “a full package of sexual and reproductive health care.” She added that even during the COVID-19 pandemic, most study participants continued to get their cabotegravir injections on schedule.

Long-acting PrEP has other advantages as well. "Injectable cabotegravir allows discrete use, only has to be administered every eight weeks, can be synchronized with some injectable family planning methods and doesn’t rely on a partner’s involvement," HPTN 084 lead investigator Mina Hosseinipour, MD, MPH, of the University of North Carolina at Chapel Hill, told POZ when the top-line results were released.

ViiV Healthcare is on track to request Food and Drug Administration (FDA) approval of long-acting cabotegravir for PrEP later this year. Last week, the FDA approved once-monthly cabotegravir injections plus an injectable version of rilpivirine, sold together under the brand name Cabenuva, as the first complete long-acting HIV treatment regimen.

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