Feminizing Hormones Don’t Affect PrEP Drug Levels

Studies offer reassurance that transgender women can safely and effectively use PrEP with hormone therapy.

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Women of trans experience seemed more likely to take HIV pre-exposure prophylaxis pills (PrEP) if they knew that feminizing hormones didn’t reduce its effectiveness, according to a drug concentration study presented at the 11th International AIDS Society Conference on HIV Science (IAS 2021).

Previous studies have shown that transgender women can benefit from PrEP if they take it consistently. But some trans women are concerned that the prevention pills can interact with hormone therapy, making one or the other less effective.

Thirty-eight transgender women in Brazil who were enrolled in the PrEParadas trial agreed to be divided into two groups. In one, 14 women took tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) PrEP for 12 weeks; in the other, 24 women took both PrEP pills and a standardized feminizing hormone regimen (estrogen in the form of estradiol valerate plus the testosterone blocker spironolactone). After the 12 weeks, all women began feminizing hormone regimens of their choice.

This pharmacokinetic (PK) study was conducted at the 12-week visit and then again between weeks 30 and 48. At PK study visits, women provided blood samples before taking TDF/FTC PrEP and then at 30 minutes, one hour, two hours, four hours, six hours, eight hours and 24 hours after dosing to assess concentrations of TDF/FTC.

During the study, none of the women acquired HIV. At week 12, nearly three out of four women (73%) had TDF/FTC levels consistent with taking four or more PrEP pills a week; 1 out of 10 (11%) had drug concentrations consistent with two to three doses a week and 16% had drug levels indicating fewer than two pills a week.

But that was a combined number based on both groups. When researchers broke down the data by feminizing hormone use, the results favored women using both PrEP and hormones during the first 12 weeks. At week 12, 64% of women in the PrEP-only group had drug concentrations in

keeping with four or more pills a week, compared with 79% of women in the PrEP plus hormone therapy group. This speaks to the question many trans women have been asking about the interaction between PrEP and hormones. This study, at least, suggests that feminizing hormones have no impact on effective drug levels of PrEP pills.

By the time the second PK measurements were taken, only 17 women were still on PrEP, but 93% of them had drug levels consistent with taking the pills four days a week or more.

“Our study suggests that oral PrEP is clinically effective among trans women with HIV risk on hormones,” said Vitoria Berg Cattani, MSc, a pharmacist at Instituto de Pesquisa Clinica Evandro Chagas in Rio de Janeiro. “And standardized and real-life [feminizing hormone treatment] do not significantly impact on tenofovir and emtricitabine exposure among trans women at risk in a long-term follow up [PK study].”

A second study by the same team looked at the effect of PrEP drugs on feminizing hormone levels. In this study, 33 women took TDF/FTC along with estradiol valerate and the testosterone blocker spironolactone. According to the study abstract, estradiol levels did not change significantly. Spironolactone levels decreased slightly but probably not enough to affect its effectiveness. “Our results reassure that oral PrEP and feminizing hormone therapy may be used concomitantly,” the researchers concluded.

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