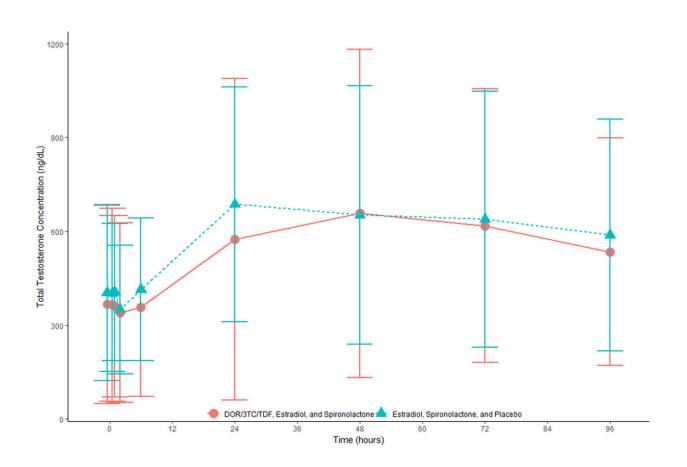


HIV medication can be used safely with gender-affirming hormone therapy

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Total testosterone concentration-time profiles with and without co-administration of doravirine, lamivudine, and tenofovir disoproxil fumarate. Data plotted represents arithmetic mean (±SD). Credit: *Clinical and Translational Science* (2024). DOI: 10.1111/cts.13721



New research definitively shows that HIV antiretrovirals can be taken together with gender-affirming hormone therapy without changing how well either drug works. The study findings can help health care providers address potential patient concerns that one drug will counteract the other.

"This study is the first head-to-head pharmacokinetic analysis of two common HIV medications and long-term feminizing hormone therapy use," says Walter Kraft, MD, director of the Division of Clinical Pharmacology at the Sidney Kimmel Medical College at Thomas Jefferson University.

"This research should help doctors reassure patients that it's safe and important to continue HIV medications alongside their hormone regimen." The study was published in *Clinical and Translational Science*.

Transgender women are at a 50 times greater risk of HIV infection than the general public, and stopping HIV <u>medication</u> can have long-term consequences, including <u>disease progression</u> to AIDS.

The study enrolled eight transgender women who were taking genderaffirming hormone therapy and who were HIV-negative. As part of the cross-over study, half of the women were asked to take one of three treatments—one after the other: first HIV therapy, then hormone therapy, and then finally, a combination of the two.

There was a 14-day "wash-out" period between each therapy when participants took no therapy. The researchers took blood and <u>urine samples</u> regularly to test for drug and hormone concentrations during and after treatment.

To ensure the order of treatments didn't affect the result, the other half of the women in the study had the treatment in the opposite order, starting with the combination hormone plus HIV therapy, followed by



hormone therapy alone, and then HIV medication alone.

Although the number of patients wasn't large, the amount of data collected on each participant was comprehensive. In addition, the use of a cross-over study design—where each participant takes each of the therapy combinations and essentially serves as her own control—provided enough statistical power to confirm the scientific validity of the findings. The duration and intensity also speak to the personal sacrifice that each participant made in order to take part in the study.

"We asked women who were HIV negative to participate because it wouldn't be ethical to ask those who are HIV positive to stop taking HIV medication," says Dr. Kraft. "We realized that it was a big ask for transgender women to halt their gender-affirming hormone therapy for the sake of science. The ones who did understood how valuable this information could be for their community. It's part of why this study is so important."

The study revealed that it is safe for patients to use HIV antiretrovirals medications together with gender-affirming hormone medications without losing potency of either drug. In fact, estrogen and testosterone levels were basically unchanged when participants also took HIV medications. "The hormone concentration in the blood was close enough that you wouldn't have to change hormone dosing at all," said first author Kevin Lam, PharmD.

"This study is so important for the trans community," says Dr. Lam.
"There's a big risk with scaling back or stopping HIV medication. The virus can develop resistance to the medications, making them ineffective at keeping the virus in check."

"We hope that this study will help reassure the trans community living



with HIV that it's safe and crucial to continue taking their antiretrovirals to control HIV infection."

More information: Kevin Lam et al, Bidirectional pharmacokinetics of doravirine, tenofovir, and feminizing hormones in transgender women (IDentify): A randomized crossover trial, *Clinical and Translational Science* (2024). DOI: 10.1111/cts.13721

Provided by Thomas Jefferson University

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