

NEW PREP DATA ON TRANSGENDER WOMEN FROM THE IPREX STUDY

Researchers from the University of California in San Francisco (UCSF) unearthed new information about PrEP usage in transgender women by taking an innovative look at the new IPREX study data. The IPREX study was a 2010 French Canadian study in mostly negative gay and bisexual men that was the first to show the positive effect of emtricitabine plus tenofovir fumarate, which is combined in one pill known as Truvada, for HIV prevention. No such efficacy was found in transgender women because their initial numbers were too small to make any definitive findings. Only 29 people were initially identified as transgender women.

This new data is the first separate analysis of transgender women that has ever occurred in a PrEP trial. Before IPREX, no other randomized controlled trial, the gold standard for making definitive conclusions, has ever specifically looked at PrEP in transgender women. This is a large step forward for transgender women who have one of the highest rates of HIV infection. A review of 22 studies indicated that approximately 28% of transgender women are HIV infected in the United States.

The IPREX study enrolled 2,499 gay and bisexual men (men who have sex with men or MSM), and transgender women in Brazil, Ecuador, Peru, South Africa, Thailand and the United States between 2007 and 2009. Because the initial results of the IPREX randomized study demonstrated that once daily Truvada prevented the risk of HIV prevention by 92% in people who actually took Truvada regularly, IPREX was extended to a non-randomized, an open label extension study that was ended in 2013. This means that everyone who wanted Truvada in the open label study received it. Blood levels of Truvada were measured to prove adherence. No one in the open label study who took Truvada at least four times per week became HIV infected during the study.

A new, more sophisticated method for determining who was transgender identified 339 transgender women which was 310 more than was originally indicated in the first IPREX study report. Fourteen percent of the 339 transgender study participants were classified as transgender women. Of this number 29 (1%) identified as women, 296 (12%) identified as trans or travesti and 14 (1%) identified as men, but reported taking feminizing hormones. Of this number, 192 participated in the open label extension, 79% of whom opted to take Truvada.

The study showed that when compared to MSM, transgender women reported much higher rates of sex work (64% v 38%), condomless receptive anal sex (86% v 55%), sexually transmitted diseases during the past six month (38% v 24%), and over five sex partners during the past three months. Transgender women had lower Truvada blood levels and were less likely to take Truvada consistently. Unlike results in MSM, there was no correlation in the consistency of Truvada use for transgender women who engaged in condomless anal sex. In the MSM population, those who engaged in condomless anal sex were more adherent to PrEP. None of the 11 transgender women who became HIV infected during the initial trial had Truvada blood levels which means they were not taking their PrEP. Two transgender women who received PrEP during the open label extension became HIV infected. In the open label study, transgender women were half as likely as MSM to have Truvada blood levels that indicated that they took Truvada at least four times per week (18% v 36%). Transgender women who took feminizing hormones were less likely to have either detectable or sufficient Truvada blood levels.

The good news is that just like MSM, transgender women who had blood levels indicating that they took Truvada four times per week did not become HIV infected. Truvada was generally well-tolerated with moderate or severe side effects rarely reported. There was no difference in adverse events in transgender women who took Truvada versus those who did not. Decreases in bone mineral density that may occur with Truvada use were less apparent in transgender women than in MSM. Researchers surmised that this may be the result of less Truvada use or a protective effect of feminizing hormones. There was also no evidence of liver toxicity.

Transgender women with consistent Truvada drug levels appeared to be protected, according to UCSF investigator Robert M. Grant, MD. Grant who stated that while the numbers of transgender study participants were still too small to draw firm conclusions, there was strong evidence pointing to PrEP efficacy.

As the trans community has long known, researchers surmised that even though PrEP seems to be effective in trans women, they have more and different barriers to PrEP use. Thus, PrEP studies for trans women should be specifically designed and tailored to their needs, rather than simply using the same studies that are designed for MSM or simply including trans women within the MSM studies as if they had the same issues and risk factors. UCSF researcher Madeline B. Deutsch, MD also acknowledged that transgender women face institutional barriers like the lack of legal protections against discrimination resulting in difficulties in employment and income inequality that cause lack of adequate food and housing. She further stated that transgender women definitely need an HIV prevention tool that they can control and which they can use without their partners' knowledge or consent. Dr. Deutsch also explained that one of the important reasons transgender women do not take their PrEP is because they are afraid it will interfere with their gender affirming hormones. She pointed out that feminizing hormones are a higher priority than PrEP.

It is perfectly clear from the UCSF findings that we need much further study in this arena. When trans women use PrEP, it appears to work, but to increase awareness, encourage continued PrEP use programs and foster research participation, interactions need to take place in safe, gender-affirming environments. The integration of PrEP and gender affirming services, including feminizing hormone services as well as the development of distinct PrEP delivery programs for trans women that are specifically designed to support trans women, and that do not lump them together with MSM programs and studies are essential to PrEP use and adherence.

We are finally headed in the right direction. Stay tuned for the latest on PrEP for HIV prevention.