Selzentry as PrEP Is Safe and Well Tolerated Among Women

This alternative to Truvada for prevention among those at high risk of HIV warrants more advanced research to determine its efficacy.

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As an alternative to Truvada (tenofovir disoproxil fumarate/emtricitabine) for use as pre-exposure prophylaxis (PrEP) among women at high risk of HIV, the antiretroviral (ARV) Selzentry (maraviroc) is safe and well tolerated, according to a recent study, Healio reports. Researchers behind the Phase II study say advanced research of Selzentry as PrEP is warranted to determine its efficacy in prevention HIV.

The controlled doubled-blind study included 188 HIV-negative women enrolled at one of 12 research sites from the HIV Prevention Trials Network and the AIDS Clinical Trials Group. The women had a median age of 35. Sixty-five percent of them were Black, 17 percent were Latina and 27 percent were white. At enrollment, the women all reported engaging in condomless vaginal or anal sex during the previous 90 days with at least one male partner who was HIV positive or of an unknown HIV status.

The women were randomly assigned to receive 48 weeks of one of four PrEP regimens: Selzentry; Selzentry and Viread (tenofovir disoproxil fumarate, which is one of the two drugs in Truvada); Selzentry and Truvada; and Truvada, which was considered the control. The women received three tablets to take daily, including matched controls when necessary; this meant that the two drugs in Truvada, Viread and Emtriva (emtricitabine), were dispensed as two pills instead of a combination pill.

Eighty-five percent of the women completed the study's follow-up, 11 percent withdrew early and 4 percent were lost to follow-up. Nineteen percent of the participants discontinued their PrEP regimen before the end of 48 weeks; there were no regimen-based differences in the rate of discontinuation among the women.

There were also no regimen-based differences in the rate of grade 3 or 4 adverse health events among the participants. A respective five, 13, nine and eight of those receiving Selzentry, Selzentry and Viread, Selzentry and Truvada, and Truvada experienced such adverse health events.

One participant died during the study, by a suicide that the researchers judged unrelated to the study drug.

As an indication of the women's adherence to their PrEP regimens, 60 percent of the plasma samples the researchers collected from the participants at week 48 had detectable drug concentrations.

None of the women contracted HIV. However, a much larger and longer-lasting trial would be required to determine the efficacy of Selzentry in preventing the virus.

To read the Healio article, click here.

To read the study abstract, click here.

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http://beta.docker.poz.com/article/selzentry-prep-safe-tolerated-among-women