Anti-HIV Vaginal Gel Study Fails Because of Poor Adherence

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A trial of a Viread (tenofovir)-containing vaginal gel to protect against HIV has failed because the South African women participants used it at such low rates. However, the gel did reduce the risk of HIV among the small subset who actually adhered to the protocol. Researchers from the FACTS 011 Phase III, multi-center, double-blind, randomized, placebo-controlled trial of a 1 percent Viread vaginal microbicide presented their findings at the 2015 Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle.

Previous research had shown that the vaginal gel could prevent male-to-female HIV transmission. But this study was required to prove the gel could work on a large scale.

Researchers recruited 3,844 HIV-negative women in nine South African sites between October 2011 and August 2014, enrolling 2,059 and including 2,029 in the primary analysis. The women were randomized to receive a Viread-containing gel or a placebo gel and instructed to insert it into the vagina before and after sex, using no more than two doses in a 24-hour period.

At their monthly study visits, the women were given HIV risk reduction counseling and were provided with condoms, along with treatment for other sexually transmitted infections. The investigators measured adherence to the gel by counting returned used applicators, as well as through tests given every three months to detect the levels of Viread in the cerivicovaginal tissues among 214 women in the Viread arm of the study. Both means of detecting adherence found that women used the gel at least half the time, with only a small proportion doing so consistently.

Across 3,036 person-years of observation, 123 women contracted the virus during the study, for an HIV incidence rate of 4.0 per 100 person-years. This included 61 women in the Viread arm and 62 in the placebo group, meaning that the Viread gel offered no protection against HIV to the group as a whole. However, among the 20 percent of women who reported using the gel for more than 72 percent of their acts of intercourse, the Viread gel lowered their risk of HIV by 57 percent.

Among the women who had their Viread levels tested, 65 percent had detectable drug in some of their samples, and 22 percent had detectable drug every time. Those who had high levels of the drug in their tissues had a 48 percent reduced risk of the virus.

Helen Rees, OBE, the FACTS 001 protocol chair and executive director of the Wits Reproductive Health and HIV Institute in Johannesburg, South Africa, said in a press release, “Interviews with participants throughout the study taught us that HIV prevention tools for women must be convenient and take account the complex social and economic realities of their lives. A product that is applied around the time of sex may be suitable for some women, but it did not meet the needs of the majority in our study, most of whom were young, single and lived with their parents. Methods that are easier for women to incorporate into their lives are likely to be more effective.”

To read the conference abstract, click here.

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