NIH modifies 'VOICE' HIV prevention study in women

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A large-scale clinical trial evaluating whether daily use of an oral tablet or vaginal gel containing antiretroviral drugs can prevent HIV infection in women is being modified because an interim review found that the study cannot show that one of the study products, oral tenofovir, marketed under the trade name Viread, is effective.

An independent data and safety monitoring board (DSMB) recommended that the Vaginal and Oral Interventions to Control the Epidemic (VOICE) study discontinue evaluating tenofovir tablets because the study will be unable to show a difference in effect between tenofovir tablets and placebo tablets. The DSMB found no safety concerns with oral tenofovir, which is currently used to treat HIV, or with the other products that will continue to be investigated as the VOICE study proceeds.

As the trial's primary sponsor, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, concurred with the DSMB's recommendation and will modify the study. Because the trial is continuing, the study data remain confidential and restricted to DSMB analysis. Given that data are unavailable, NIAID cannot speculate about why oral tenofovir did not show an effect among VOICE study participants.

Begun in September 2009, the VOICE study, or MTN-003, involves more than 5,000 HIV-uninfected women in South Africa, Uganda and Zimbabwe. The trial was designed to test the safety, effectiveness and

acceptability of two different HIV prevention strategies: an investigational microbicide gel containing tenofovir, and oral tablets containing tenofovir either alone or co-formulated with the drug emtricitabine. The tablets, known by the brand names Viread (tenofovir) and Truvada (tenofovir plus emtricitabine), have been taken daily in an approach known as pre-exposure prophylaxis, or PrEP.

After its routine review of the study data on Sept. 16, the DSMB recommended that the investigators stop evaluating oral tenofovir because the study would be unable to show that tenofovir tablets have a different effect than placebo tablets at preventing HIV infection among the study participants. The DSMB therefore recommended that the roughly 1,000 women in the oral tenofovir group stop taking the study product. Further, the DSMB recommended that the VOICE study continue as designed to evaluate tenofovir gel and oral Truvada.

The study team will immediately begin to inform all VOICE participants of this new development and will soon begin the orderly discontinuation of the tenofovir tablets. Participants who were taking oral tenofovir will stop using the product at their next scheduled clinical site visit. They will then return eight weeks later for a final set of tests and procedures before exiting the study. At that visit, they will be provided information about where they can continue to receive HIV testing and counseling, contraception and other medical and support services.

NIAID is pleased that the trial will continue to examine the question of whether tenofovir gel and oral Truvada are safe and effective HIV prevention measures for women and thanks all participants in the VOICE study for their significant contribution to furthering HIV prevention research. This study is an important component of NIH's comprehensive HIV prevention research program articulated in the HHS National HIV/AIDS Strategy Operational Plan.

NIAID remains committed to supporting research to develop HIV prevention tools that women can implement. Slightly more than half of all new HIV infections globally occur in women, mostly through unprotected sex with HIV-infected men. A safe and effective microbicide or oral PrEP regimen would be particularly helpful to women when it is difficult or impossible for them to refuse sex or negotiate condom use with their male partners.

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