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United States Contact
Yasmin Halima
+1 202 257 5483
yhalima@path.org

South Africa Contact
Samu Dube
+ 27 11 447 1641
sdube@path.org

Kenya Contact
Pauline Irungu
+ 254 20 387 7177
pirungu@path.org

Global Campaign News

Pivotal HIV prevention trial for women in Africa finds that use of tenofovir gel does not prevent HIV: What does this mean for HIV prevention for women?

Global Campaign for Microbicides statement on the VOICE DSMB decision to discontinue use of tenofovir gel

Johannesburg, South Africa, and Washington, DC, November 28, 2011–A pivotal trial testing daily use of oral and topical prophylaxis to help prevent HIV has made a decision to discontinue testing tenofovir-containing vaginal gel, according to an announcement by the Microbicide Trials Network (MTN). The VOICE study (Vaginal and Oral Interventions to Control the Epidemic), sponsored by the National Institute of Allergy and Infectious Diseases, part of the US National Institutes of Health (NIH), began in September 2009 to evaluate the safety and efficacy of two antiretrovirals (tenofovir and Truvada®) taken daily as oral pre-exposure prophylaxis (PrEP) in women, as well as a vaginal microbicide containing tenofovir in gel form. The study is taking place at sites in South Africa, Uganda, and Zimbabwe.

A meeting of the independent Data and Safety Monitoring Board (DSMB) for VOICE on November 17, 2011 recommended that the tenofovir gel arm be dropped from the study because daily use of the gel did not show effectiveness in preventing HIV in women enrolled in the trial. The study found that the rates of HIV infection that occurred in women were similar in both the gel and placebo groups, at 6% and 6.1% incidence respectively. In September 2011, another DSMB review recommended that women assigned to the tenofovir tablet should discontinue use of the study product on the grounds that continuing its use would not demonstrate a difference in effectiveness between tenofovir and placebo. Neither decision reflected concerns around safety of use of tenofovir in either tablet or gel form.

In this recent evaluation, the DSMB also recommended that the study continue evaluating Truvada®, a combination pill containing tenofovir and emtricitabine, to determine whether it may be effective in preventing HIV compared to placebo.

Interestingly, the results did not reflect findings from the CAPRISA 004 study, which was also designed to test the effectiveness of tenofovir gel but used before and after sex instead of daily. Last year, CAPRISA announced that tenofovir gel was 39% effective in preventing HIV compared to placebo in the 889 women enrolled in the trial in KwaZulu Natal, South Africa. Although there were 39% fewer infections in women using tenofovir gel in CAPRISA 004, the study reported statistical analysis that confirmed that the true level of effectiveness of tenofovir gel when used before and after sex could in fact have been anywhere between 6% and 60%.

The difference in outcomes from the two studies will only be understood with more detailed analysis, but diversity in the population groups, ages of the women, adherence, or a host of other factors could have played a part. VOICE was also a much larger study, with more than 2,000 women enrolled in either tenofovir gel or placebo, potentially giving us a deeper insight into the efficacy of the gel.

MTN, NIH, and others that have sponsored ongoing or planned tenofovir gel-related studies are currently reviewing the impact of the VOICE findings on their trials going forward. A study by the South African-led clinical research consortium FACTS announced its plans to move forward with its study, FACTS 001, which will test use of tenofovir gel before and after sex—the same regimen as CAPRISA 004, but with a larger enrollment target of 2,200 women.

Responding to the decision by the VOICE DSMB, Yasmin Halima, Director of the Global Campaign for Microbicides, noted: “This is truly disappointing news—disappointing for all those who strive to develop tools

for HIV prevention, and most of all, for women around the world, particularly those most vulnerable to HIV. It's not the answer we had hoped for, but it will provide more information to help us better understand what may or may not work."

Professor Gita Ramjee of the South African Medical Research Council, co-investigator for the VOICE South Africa trial site and member of the Global Campaign for Microbicides Steering Committee, reflected on the need to continue the search for HIV prevention options for women: "Even as we express our disappointment," she said, "let us remember that the crucial insights we gain from VOICE will serve to advance the field. The urgency of the epidemic in my country—and its devastating impact on women—leaves no choice but for us to continue our search until we find effective tools to offer women as protection from HIV."

Samukeliso Dube, Head of Africa Programs for the Global Campaign for Microbicides, agreed: "The need to develop tools to protect women from HIV is now more vital than ever. We need research that will help us better understand how these drugs work in women, whether age and circumstances indeed make a difference to their use and acceptability; and importantly, we need to test different modalities, including vaginal rings, long-acting injectables, and microbicides that combine drugs—just as we did for HIV treatment."

Another Phase III study by MTN, planned for launch next year, will test the safety and efficacy of a slow-release vaginal ring developed by the International Partnership for Microbicides, which contains a different antiretroviral, dapivirine. Enrolling more than 3,000 women in Southern and Eastern Africa, the study will test the impact of a monthly vaginal ring on reducing HIV infection.

About the trial

VOICE
Partners PrEP
US Centers for Disease Control and Prevention TDF2 study
FACTS 001
CAPRISA

About pre-exposure prophylaxis

Pre-exposure prophylaxis, or PrEP, is the use of medicine in advance of exposure to something potentially harmful, such as a disease or condition. Within the context of HIV, it is the use of antiretroviral medicine by HIV-negative people before sexual activity or other high-risk behaviors.

About microbicides

Microbicides are being developed as products that could be topically applied by a receptive sex partner to reduce the risk of becoming HIV infected during sex. Microbicide candidates are being formulated as vaginal gels, suppositories, and slow-release vaginal rings.

About the Global Campaign for Microbicides (www.global-campaign.org)

The Global Campaign for Microbicides is a civil society organization working to ensure the ethical and accelerated development of, and widespread access to, new and existing HIV-prevention options—especially for women. For more information on microbicides, please email info@global-campaign.org.