Clinical trial of antiretroviral-based HIV prevention strategies for women now under way

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A new, large-scale clinical trial is examining whether antiretroviral medications normally used to treat HIV infection can also prevent HIV infection in women when applied as a vaginal gel or taken as oral tablets once daily.

The study, called Vaginal and Oral Interventions to Control the Epidemic (VOICE) or MTN-003, will involve up to 5,000 HIV-uninfected women at risk for HIV infection in four African countries. The trial will test the safety and efficacy of two different HIV prevention strategies: an investigational microbicide gel containing the antiretroviral drug tenofovir, and oral tablets containing tenofovir or a combination of tenofovir and emtricitabine known by the brand name Truvada. The tablets would be taken prior to exposure in an approach known as pre-exposure prophylaxis, or PrEP. Testing a microbicide and PrEP in the same trial will enable scientists to directly compare the two strategies in terms of their safety and acceptability.

Notably, the VOICE study is the first efficacy study of an investigational microbicide in which participants apply the gel once daily rather than shortly before sexual intercourse. If found effective, this approach would allow participants to choose whether to use the gel in association with sexual activity or at another time of day, permitting greater privacy and convenience of use.

"We need multiple, scientifically proven HIV prevention strategies acceptable to different populations to effectively combat the spread of the virus, and PrEP and microbicides are two promising approaches that we are actively pursuing," says Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID). "The VOICE study is designed to answer multiple crucial questions about these experimental interventions, with an emphasis on protecting women from HIV."

NIAID is sponsoring and funding the trial with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the National Institutes of Health. Co-sponsors are Gilead Sciences Inc. of Foster City, Calif., and CONRAD of Arlington, Va. The NIH-funded Microbicide Trials Network is conducting the study.

Women make up half of all people worldwide living with HIV, and in sub-Saharan Africa, women represent nearly 60 percent of adults living with the virus. In most cases, women become infected with HIV through sexual intercourse with an infected male partner. An effective microbicide or PrEP regimen could give women an HIV prevention method they control. This would be particularly helpful in situations where it is difficult or impossible for women to refuse sex or negotiate condom use with their male partners.

The VOICE study is being conducted at 14 sites in South Africa, Uganda, Zambia and Zimbabwe. The Phase IIb study, which will last approximately three and a half years, is being led by Zvavahera Mike Chirenje, M.D., of the University of Zimbabwe in Harare, and Jeanne Marrazzo, M.D., M.P.H., of the University of Washington in Seattle. The sexually active, HIV-uninfected women ages 18 to 45 participating in the study will be randomly assigned to one of five regimens, each performed once daily:

- applying tenofovir gel vaginally
- applying a placebo gel vaginally
- taking a tenofovir pill and a placebo pill
- taking a tenofovir/emtricitabine pill and a placebo pill
- taking two placebo pills

Neither the investigators nor the participants will know who receives the active gel or tablets and who receives the placebos. Gilead Sciences is providing tenofovir and tenofovir/emtricitabine tablets at no cost, and CONRAD is providing tenofovir gel and gel applicators free of charge.

Study staff will follow the participants for 14 to 35 months. The investigators will compare the number of women in each group who acquire HIV during the study to determine whether the microbicide or either PrEP regimen is markedly more effective than the corresponding placebo in preventing HIV infection.

Safety will be monitored closely throughout the study. Designed according to the most rigorous standards of international medical practice and ethics, the VOICE study contains numerous measures, beginning at the site level, intended to protect the safety and well-being of participants. This includes a multi-tiered safety review process with strict U.S. and international procedures for monitoring and reporting of adverse events. Also, all participants will receive regular HIV testing and risk-reduction counseling; condoms; and testing for sexually transmitted infections. Staff will refer any participant who acquires HIV or a sexually transmitted infection during the study to appropriate treatment

and care in her community.

In addition to testing tenofovir gel and PrEP for safety and efficacy, the VOICE study aims to determine which regimen—pill or gel—women are likely to follow more consistently, and whether either intervention influences participants' risk-taking behavior. The study also will assess how frequently participants who acquire HIV during the trial develop resistance to tenofovir or tenofovir/emtricitabine.

The premise behind PrEP is that taking an antiretroviral drug before exposure to HIV could potentially inhibit HIV replication immediately after exposure to the virus, thwarting permanent infection. This strategy is used globally to successfully prevent the transmission of HIV from mother to infant.

A companion study at the Uganda and Zimbabwe clinical trial sites involving 300 women assigned to the tablet groups will examine the potential effects, if any, of oral tenofovir on bone density in HIV-uninfected women. A second companion study will examine household and community-level factors associated with adherence to the VOICE study products.

Source: NIH/National Institute of Allergy and Infectious Diseases (news : web)

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