

Anti-HIV gel shows promise in large-scale study in women

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An investigational vaginal gel intended to prevent HIV infection in women has demonstrated encouraging signs of success in a clinical trial conducted in Africa and the United States. Findings of the recently concluded study, funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, were presented today at the Conference on Retroviruses and Opportunistic Infections in Montreal.

The study investigators found the microbicide gel—known as PRO 2000 (Indevus Pharmaceuticals, Inc., Lexington, Mass.)—to be safe and approximately 30 percent effective (33 percent effectiveness would have been considered statistically significant). This is the first human clinical study to suggest that a microbicide—a gel, foam or cream intended to prevent the sexual transmission of HIV and other sexually transmitted infections when applied topically inside the vagina or rectum—may prevent male-to-female sexual transmission of HIV infection.

"Although more data are needed to conclusively determine whether PRO 2000 protects women from HIV infection, the results of this study are encouraging," says NIAID Director Anthony S. Fauci, M.D.

The Phase II/IIb clinical trial, which enrolled more than 3,000 women, is NIH's first large clinical study of a microbicide.

"An effective microbicide would be a valuable tool that women could use to protect themselves against HIV and one that could substantially

reduce the number of new HIV infections worldwide," Dr. Fauci adds.

"The study, while not conclusive, provides a glimmer of hope to millions of women at risk for HIV, especially young women in Africa," adds lead investigator Salim S. Abdool Karim, MBChB, Ph.D., from the Center for the AIDS Program of Research in South Africa, who presented the findings at CROI. "It provides the first signal that a microbicide gel may be able to protect women from HIV infection."

Currently, women make up half of all people worldwide living with HIV. In sub-Saharan Africa, women represent nearly 60 percent of adults living with HIV, and in several southern African countries young women are at least three times more likely to be HIV-positive than young men. In most cases, women become infected with HIV through sexual intercourse with an infected male partner. An effective microbicide could provide women with an HIV prevention method they initiate. 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 study, known as HPTN 035, began in 2005 and enrolled 3,099 women at six sites in Africa and one in the United States. The clinical trial tested two candidate microbicide gels for safety and their ability to prevent HIV infection: PRO 2000 (0.5 percent dose), and BufferGel (ReProtect Inc., Baltimore). The U.S. Agency for International Development provided funding to manufacture BufferGel for the HPTN 035 study. PRO 2000 inhibits the entry of HIV into cells; BufferGel boosts the natural acidity of the vagina in the presence of seminal fluid, which can help to inactivate HIV and other pathogens.

The volunteers in HPTN 035 were divided at random into four equal-sized groups:

- Those using BufferGel prior to engaging in sexual intercourse
- Those using PRO 2000 before engaging in sexual intercourse
- Women using placebo gel prior to engaging in sexual intercourse
- Those who did not use gel before engaging in sexual intercourse

All participants received detailed information about the possible risks and benefits of trial participation before enrollment and were monitored monthly while in the study, which averaged 20 months. In addition, all the women were counseled on safe sex practices, given condoms, and tested and treated for sexually transmitted infections throughout the study.

Participants reported regular use of the investigational gels (81 percent of sex acts) and nearly all (99 percent) said they would use the products if approved for HIV prevention. Condom usage was also high throughout the course of the trial (74 percent).

In the final analysis, 194 women in the study became infected with HIV. Of these infections, 36 occurred in the PRO 2000 group, 54 in the BufferGel group, 51 in the placebo group and 53 in those who did not use gel. Based on these data, PRO 2000 was 30 percent effective, while BufferGel had no detectable preventive effect on HIV infection. Both PRO 2000 and BufferGel were found to be safe.

HPTN 035 was conducted by the Microbicide Trials Network (MTN), an HIV/AIDS clinical trials network established in 2006 by NIAID with co-funding by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the NIH. Prior to the establishment of the MTN, the study was led by the NIAID-funded HIV Prevention Trials Network (HPTN), from which the study gets its name.

Roberta J. Black, Ph.D., chief of the Microbicide Research Branch in

NIAID's Division of AIDS, says, "Although a statistically significant protective effect was not observed, HPTN 035 successfully met its goal of determining whether either of the two candidate microbicides had sufficient promise to be considered for testing in a larger Phase III clinical study."

Study participants are being informed of the findings and counseled on the continued need to follow safe sex practices in order to avoid possible HIV exposure. Women who became infected with HIV during the trial were counseled and referred to appropriate medical care and support, including antiretroviral therapy. These same women were also given the opportunity to participate in MTN 015, a clinical study examining the nature of HIV progression and treatment response in HIV-infected women who were using topical microbicides or oral antiretrovirals as an HIV preventive measure when they acquired HIV infection.

A separate clinical study sponsored by the Medical Research Council (MRC) and the Department for International Development of the United Kingdom that is currently testing PRO 2000 (0.5 percent dose) in preventing HIV infection among women in Africa could provide further insight into the microbicide's effectiveness. That Phase III study involving nearly 9,400 women is set to conclude in August 2009.

For more information about the HPTN 035 clinical study, see www3.niaid.nih.gov/news/QA/HPTN_035_qa.htm .

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