

Clinical trial finds microbicide promising as HIV prevention method for women

March 5 2009

A clinical trial involving more than 3,000 women in the U.S. and southern Africa demonstrates for the first time the promise of a vaginal microbicide gel for preventing HIV infection in women. According to findings presented at the Conference on Retroviruses and Opportunistic Infections (CROI), one 0.5 % dose of a microbicide designed to prevent HIV from attaching to cells in the genital tract, was 30% effective. While the results are encouraging, researchers on the study, known as HPTN 035, report that additional evidence is needed to determine more definitively its effectiveness.

"These findings provide the first signal that a microbicide gel may be able to prevent women from HIV infection," says Salim S. Abdool Karim, MD, PhD, professor of clinical Epidemiology at Columbia University Mailman School of Public Health, pro vice-chancellor (research) at the University of KwaZulu-Natal in Durban, South Africa, and director the Center for the AIDS Program of Research in South Africa, who led the multi-center study for the U.S.-based Microbicide Trials Network (MTN). "Indeed, for the millions of women at risk for HIV, especially young women in Africa, there is now a glimmer of hope. But these findings also indicate that more research is needed; we can't yet say that we have an effective microbicide."

Microbicides are substances intended to reduce or prevent the sexual transmission of HIV and other sexually transmitted infections when applied topically. Several candidate microbicides are being tested in clinical trials, although none is yet approved or available for use. Earlier

trials have yielded disappointing results or were stopped prematurely.

Currently, women comprise half of all people worldwide living with HIV. In sub-Saharan Africa, women represent nearly 60 % 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. Although correct and consistent use of male condoms has been shown to prevent HIV infection, women often cannot negotiate condom use with their male partners. An effective microbicide could provide women with an HIV prevention method they initiate.

HPTN 035 evaluated the safety and effectiveness of two candidate microbicides for preventing male-to-female sexual transmission of HIV. The study was conducted between February 2005 and September 2008 and involved 3,099 women at six sites in Africa and one in the United States. In Africa, the sites were located in Durban and Hlabisa, KwaZulu-Natal, South Africa; Harare, Zimbabwe; Lusaka, Zambia; Blantyre, Malawi; and Lilongwe, Malawi. The U.S. site was in Philadelphia.

"I am particularly impressed by and grateful to the women who took part in HPTN 035," commented Sharon Hillier, PhD, vice chairman and professor, department of obstetrics and gynecology and reproductive sciences at the University of Pittsburgh School of Medicine, and MTN principal investigator. "We have reached an important milestone in HIV prevention research, and these women deserve credit for the success of the study."

Source: Columbia University's Mailman School of Public Health

Citation: Clinical trial finds microbicide promising as HIV prevention method for women (2009, March 5) retrieved 3 May 2024 from <https://medicalxpress.com/news/2009-03-clinical-trial-microbicide-hiv-method.html>

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