
EMBARGOED TILL JULY 20TH, 1PM CENTRAL EUROPEAN SUMMER TIME/13h00 SOUTH AFRICAN STANDARD TIME/7AM U.S. EASTERN DAYLIGHT TIME

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STUDY OF MICROBICIDE GEL SHOWS REDUCED RISK OF HIV & HERPES INFECTIONS IN WOMEN

DURBAN, SOUTH AFRICA and VIENNA, AUSTRIA (July 20, 2010) — UKZN researchers have achieved an important scientific breakthrough in the fight against HIV and genital herpes with a vaginal gel that significantly reduces a woman’s risk of being infected with these viruses. The results of the ground-breaking safety and effectiveness study of an antiretroviral microbicide gel study were reported today by the Centre for the AIDS Programme of Research in South Africa (CAPRISA) at the XVIII International AIDS Conference in Vienna, Austria.

The microbicide containing 1% tenofovir—an antiretroviral drug widely used in the treatment of HIV—was found to be 39% effective in reducing a woman’s risk of becoming infected with HIV during sex and 51% effective in preventing genital herpes infections in the women participating in the trial. Should other studies of tenofovir gel confirm these results, widespread use of the gel, at this level of protection, could prevent over half a million new HIV infections in South Africa alone over the next decade.

“Tenofovir gel could fill an important HIV prevention gap by empowering women who are unable to successfully negotiate mutual faithfulness or condom use with their male partners,” said study co-principal investigator, Dr. Quarraisha Abdool Karim, Associate Director of CAPRISA and Associate Professor of Epidemiology at Columbia University. “This new technology has the potential to alter the course of the HIV epidemic, especially in southern Africa where young women bear the brunt of this devastating disease.”

Tenofovir works by preventing HIV from growing inside human cells. Taken in pill form, tenofovir is a common component of various three-drug cocktails that are used to treat HIV infections. The new results now indicate that tenofovir formulated as a topical gel and inserted into the female genital tract also has great promise for use in HIV and herpes simplex virus type-2 (HSV-2) prevention.

The CAPRISA 004 trial of tenofovir gel involved 889 women at high risk of HIV infection at an urban and a rural site in KwaZulu-Natal, South Africa. Overall, 98 women out of the 889 became HIV positive during the trial—with 38 in the tenofovir gel group and 60 in the placebo gel group. Out of the 434 women who tested negative for herpes at the start of the trial, 29 became infected in the tenofovir group and 58 became infected in the placebo group. The reduced rates of HIV and herpes infections among the women who used the tenofovir gel are statistically significant.

“Tenofovir gel has a potential dual effect in preventing HIV. Since women with genital herpes are much more likely to become infected with HIV, the additional protection of tenofovir gel against herpes creates a second mechanism whereby the gel may have a bigger impact in preventing HIV,” said study co-principal investigator, Dr Salim S. Abdool Karim, Director of CAPRISA and Pro Vice-Chancellor (Research) of the University of KwaZulu-Natal, South Africa. “The trial results are a significant first step toward establishing

the effectiveness of antiretroviral drugs for HIV and genital herpes prevention; confirmatory studies are now urgently needed.”

During monthly visits, all participants were provided with HIV risk-reduction counseling, condoms and treatment for sexually transmitted infections, and each was clinically examined for potential side effects and tested for HIV infection. The study was double-blinded and neither the researchers nor the participating women knew whether a woman in the study received tenofovir gel or placebo gel. Women in the study were advised to use the gel up to 12 hours before sex and soon after having sex for a maximum of two doses in 24 hours – a dosing strategy referred to as BAT24. Participants used the gel for a minimum of one year and a maximum of two and a half years. The trial team observed no substantive safety concerns from use of the gel. Further, no increase in risky behavior was observed in the women.

The CAPRISA researchers also found that the protective effect against HIV and genital herpes increased as use of the tenofovir gel increased. Women who used the gel in more than 80% of their sex acts had a 54% reduction in HIV infections, whereas those who used the gel in less than half of their sex acts had a 28% reduction in HIV infections. Among those women who became infected, tenofovir gel had no effect on the amount of HIV in their bloodstream at the time of infection. Also, none of the women who became infected with HIV showed resistance to tenofovir.

Professor Malegapuru Makgoba, Vice-Chancellor of the University of KwaZulu-Natal stated, “This piece of research is a significant milestone for women in the thirty year history of the HIV/AIDS epidemic, microbicides and antiretroviral research. The research represents that which is best in science with direct translation into prevention policy, bringing a message of hope and empowerment to women, policymakers and scientists. These research findings will not only significantly alter the shape and form but also the future direction of this devastating epidemic.”

All volunteers to the study who tested HIV positive were provided care including ARV treatment at the CAPRISA clinics and women who became infected during the study were enrolled into CAPRISA studies and/or the CAPRISA AIDS treatment program at their respective sites for ongoing care and support.

This study was jointly funded by the Governments of South Africa and the United States, through the Technology Innovation Agency (TIA) and the US Agency for International Development (USAID), respectively. USAID provided \$16.5M and TIA provided \$1.1 for the study. "USAID is proud to be the major donor of this first-ever proof of concept that a vaginal microbicide can effectively and safely reduce the risk of HIV transmission from men to vulnerable women. The success of the CAPRISA 004 trial perfectly complements the Global Health Initiative and our focus on women's health, both in prevention and sustainable health delivery systems," stated USAID Administrator Raj Shah.

The promising findings of the CAPRISA 004 study is only a first step in determining if tenofovir gel is effective in preventing HIV and herpes infection; additional studies are urgently needed to confirm and extend the findings of the CAPRISA study. Important information is expected from current studies such as the Microbicide Trials Network’s VOICE study, which is currently assessing daily tenofovir gel as well as daily tenofovir and Truvada tablets in women in several African countries. Studies of daily Truvada tablets are underway in intravenous drug users, young high-risk women and men who have sex with men.

“We are proud to have partnered with CAPRISA and CONRAD on this important study. We see it as a major victory in the field of HIV prevention research. This is the first evidence that an antiretroviral drug in a gel form – a microbicide – can reduce HIV and genital herpes infection in women,” said Ward Cates, President of FHI. “The next step is to see whether other studies underway confirm these exciting results.”

Only after drug regulatory authorities determine that tenofovir gel is safe and effective for HIV prevention, can the gel be made available to the public for HIV prevention. Since this process can take



several years, TIA and U.S.-based CONRAD are working together to address the challenges to making the gel available first to women in South Africa.

"CONRAD has given the rights to manufacture this gel to the government of South Africa to get this much needed product to women in South Africa as rapidly as possible," said Dr. Henry Gabelnick, Executive Director of CONRAD, who provided the gel for the study. "The Technology Innovation Agency (TIA) is working closely with the South African government, CAPRISA and CONRAD to ensure that this important innovation makes an impact in preventing the spread of HIV/AIDS," said Dr. Mamphela Ramphele, Chairperson of TIA.

Ambassador Eric Goosby, U.S. Global AIDS Coordinator said, "The results of the CAPRISA trial provide new hope and direction for not only HIV prevention, but also broader efforts under the Global Health Initiative. We recognize that microbicides will be a great asset to HIV prevention efforts, and the U.S. Government is pleased to support this important research."

"The trial's findings create a new vision for the opportunity for prevention of HIV and re-define the public health approach to HIV control," added Dr Linda Fried, Dean of the Mailman School of Public Health of Columbia University, New York.

The trial was conducted by CAPRISA in partnership with the U.S.-based organizations FHI and CONRAD with funding from USAID. Gilead Sciences donated the active ingredient for the manufacture of the tenofovir gel.

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CAPRISA (www.caprisa.org) is an AIDS research institute of the University of KwaZulu-Natal and Columbia University. Its headquarters are at the Nelson R Mandela School of Medicine, University of KwaZulu-Natal in Durban, South Africa. CAPRISA is a designated UNAIDS Collaborating Centre for HIV Prevention Research. The main goal of CAPRISA is to undertake globally relevant and locally responsive research that contributes to understanding HIV pathogenesis, prevention and epidemiology, as well as the links between tuberculosis and AIDS care. CAPRISA comprises four research programmes: HIV pathogenesis & vaccines, HIV and TB treatment, Microbicides, and HIV prevention and epidemiology.
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UKZN (www.ukzn.ac.za) Globally the University of KwaZulu-Natal (UKZN) is ranked as one of three African universities in the top 500. The University is a multi-campus, residential, teaching and research university, based in KwaZulu-Natal, South Africa. It is rated as one of the top three in research output in South Africa and is structured into four Colleges, each comprising two cognate faculties. The university is located on five campuses and has over 40 000 students of whom approximately 31 707 are undergraduate and 8 330 are postgraduate. As one of South Africa's pre-eminent research institutions, the university provides a dynamic environment for all facets of the research and innovation spectrum.
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Technology Innovation Agency, formerly known as LIFElab (www.tia.org.za) TIA was formed from a merger of several DST funded instruments, including LIFElab. TIA is mandated to stimulate and intensify technological innovation in order to improve economic growth and the quality of life of all South Africans by developing and exploiting technological innovations. To this end, TIA is set up to be a world class innovation agency that supports and enables technological innovation to achieve socio-economic benefits for South Africa through leveraging strategic partnerships.
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FHI (www.fhi.org) is a global health and development organization whose rigorous, science-based approach builds programs that create lasting change. Founded in 1971, FHI maintains offices and staff worldwide, helping to forge strong local relationships that enable us to make measurable progress against disease, poverty, and inequity—improving lives for millions. FHI was the primary recipient of USAID funds for the project and provided scientific and operational expertise to the South African scientists in the CAPRISA 004 trial.

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CONRAD (www.conrad.org) was established in 1986 and is a Division of the Department of Obstetrics and Gynecology at Eastern Virginia Medical School (EVMS) in Norfolk, VA, where it has laboratories and a clinical research center. The main office is located in Arlington, VA with additional offices in West Chester, PA and collaborators around the world. CONRAD is committed to improving reproductive health by researching and developing new contraceptive options and products to prevent HIV and STI infections.

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USAID (www.usaid.gov) is an independent federal government agency that receives overall foreign policy guidance from the Secretary of State. With headquarters in Washington, D.C., USAID’s strength is its field offices around the world. We work in close partnership with private voluntary organizations, indigenous organizations, universities, American businesses, international agencies, other governments and other U.S. government agencies. USAID has working relationships with more than 3,500 American companies and over 300 U.S.-based private voluntary organizations.

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