

Sample of Study “Backgrounder”



Backgrounder

Family Health International Study of Daily Oral Tenofovir to Prevent HIV among Women at High Risk of Infection

Since 2004, Family Health International has been working in Africa to study whether a widely used HIV treatment drug, called tenofovir, can also prevent HIV in women who are at high risk of HIV infection. In particular, researchers have looked at the drug’s safety and effectiveness in preventing HIV infection in these women.

This study is important because a new HIV prevention approach, such as using a drug like tenofovir to prevent infection, could be used with other prevention strategies such as condoms to substantially reduce the number of people who become infected with HIV worldwide. It could make an especially large impact in Africa, where more than 70 percent of all HIV infections occur, and would be of particular benefit to people who have difficulty negotiating condom use.

The FHI study involved heterosexual women from the African countries of Ghana, Cameroon, and Nigeria who had multiple sex partners. Because the women were at high risk of being infected with HIV, they were also the most likely to benefit from tenofovir if it can be shown to safely and effectively prevent HIV.

Tenofovir is not a new drug. It has already been tested in thousands of HIV-infected people, it is approved by regulatory agencies, and it is being used in an oral form in many countries for HIV treatment. The FHI study is among the first to begin testing the oral form for both safety and effectiveness in preventing HIV infection.

The study was designed according to the most rigorous international ethical standards. It was approved by institutional review boards at Family Health International and by regulatory authorities in the countries where the study took place.

Half of the participants received daily oral tenofovir and half received a daily placebo, which is a pill that looks and tastes like tenofovir but does not contain any drug. At monthly visits during the study, participants received HIV prevention counseling, were given condoms to use during all sexual acts, and were provided treatment for any symptomatic sexually transmitted infections, all actions which have been shown to reduce the risk of HIV infection.

Liver and kidney functioning were evaluated every three months to confirm the safety of tenofovir for HIV-uninfected individuals and to identify any possible side effects of the drug. Participants were also tested for HIV each month to determine the drug’s effectiveness at preventing HIV. Those who became infected with HIV during the study were provided enhanced referral to care and support services in their communities, including

access to care that involves antiretroviral drug provision when needed. Local investigators identified facilities within each country that offer low-cost, HIV-related psychological, social, and medical services. HIV-positive participants were counseled and referred to those sites. Those who experienced medical problems that were directly related to their participation in the trial received medical services free of charge.

If this or other tenofovir studies conclusively demonstrate that tenofovir is safe and effective for preventing HIV, then Gilead Sciences, the U.S.-based manufacturer of tenofovir, has agreed to provide the drug at a no-profit cost to HIV prevention programs in resource-poor countries. Gilead has provided tenofovir free of charge for the FHI study, which is being supported by a grant awarded to Family Health International in 2002 by the Bill & Melinda Gates Foundation. Preliminary results will be available August 17, 2006, at the International AIDS Conference in Toronto. Final results will be submitted for publication in 2006.

For more information on Family Health International, see <http://www.fhi360.org>.

Family Health International is dedicated to improving lives, knowledge, and understanding worldwide through a highly diversified program of research, education, and services in family health and HIV/AIDS prevention, care, and treatment. Since its inception in 1971, FHI has formed partnerships with national governments and local communities in countries throughout the developing world to support lasting improvements in the health of individuals and the effectiveness of entire health systems. FHI has a staff of 1600 and offices in nearly 40 countries.