



CONTACTS: Lisa Rossi
+1-412-641-8940
+1- 412- 916-3315 (mobile)
rossil@upmc.edu

Clare Collins
+1-412-641-7299
+1-412-770-8643 (mobile)
collcx@upmc.edu

FACT SHEET

Oral Pre-Exposure Prophylaxis (PrEP) to Prevent HIV

Fast Facts

- Oral pre-exposure prophylaxis (PrEP) is an HIV prevention approach that involves use of medicines to treat HIV called antiretrovirals, or ARVs, by people who are HIV-negative. The idea behind PrEP is that taking an ARV routinely – daily, for example –can help prevent infection in people who come in contact with the virus, such as through unprotected sex.
- ARVs have been used successfully to treat millions of HIV-infected people worldwide. Because ARVs are effective in treating HIV, the hope is that they can work to prevent HIV infection as well.
- A large-scale trial in nearly 2,500 gay men and other men who have sex with men provided the first-ever evidence that oral PrEP can indeed help reduce HIV risk. Study participants who took a daily ARV tablet called Truvada[®], together with comprehensive HIV prevention services and counseling, had 44 percent fewer infections than men who received a placebo tablet.
- More information is needed before PrEP can be considered for widespread use. Trials of PrEP are ongoing in different at-risk populations, including women.
- No one approach will ever be 100 percent effective against HIV or acceptable for use by all people. A combination of safe and effective methods will be needed to address the global impact of HIV.

The ARVs Being Used for Oral PrEP

At the present time, both current and planned trials of oral PrEP are focused on two ARVs approved for the treatment of HIV: tenofovir and Truvada. Tenofovir's full name is tenofovir disoproxil fumarate (TDF). It is also known by the brand name Viread[®]. Truvada is a combination drug that contains tenofovir and emtricitabine (FTC). Truvada is sometimes referred to as TDF/FTC.

When used in combination with other ARVs, a regimen called antiretroviral therapy (ART), both tenofovir and Truvada are generally safe and effective for improving the health of people with HIV. Serious side effects are rare, but can include liver function problems, kidney damage or failure, or reduction in bone mineral density.

Less is known about the safety and side effects of these drugs in people who are HIV-negative, but recent studies indicate they are infrequent and mild. As a precaution, researchers conducting oral PrEP trials carefully screen potential participants to ensure no one is enrolled with a medical condition or history precluding safe use of a study drug. Participants enrolled in these trials are closely monitored by investigators throughout.

Determining the Promise of PrEP

HIV can be transmitted in different ways, such as through unprotected vaginal or anal sex, or by sharing needles with an injecting drug user who is infected with HIV. An intervention like PrEP may not be effective in all at-risk populations, which is why studies must be conducted in each of these different groups.

This kind of research, called a clinical trial, must follow stringent ethical and scientific guidelines and be conducted under the watchful eye of regulatory and research authorities. There are several phases to HIV clinical trials. Phase I trials evaluate safety in a small number of people who receive the study product for short periods, say, one to two weeks. If results of a Phase I study suggest the product is safe, the study progresses to a Phase II trial, in which researchers continue to track safety over longer periods of time in a larger number of people. Phase IIb and Phase III trials are performed to determine how well the study product works and conducted in large numbers of people, usually at multiple research centers. Data from Phase IIb

-more-

and Phase III trials are often used by regulatory agencies to determine if a particular product should be approved for widespread use.

Results of PrEP Studies

- A Phase II study conducted by the U.S. Centers for Disease Control and Prevention (CDC) to assess oral PrEP in 400 HIV-negative gay men and other men who have sex with men found taking tenofovir daily did not cause any significant side effects that would make the product unsafe. The researchers also noted that the men in the study did not increase risky sexual behaviors, addressing a concern that people using PrEP might have a false sense of security, and be less likely to use condoms.
- **iPrEx**, a large-scale Phase III trial, showed that daily use of Truvada can help reduce the risk of HIV infection among men who have sex with men, who bear the burden of the epidemic in many parts of the world. Overall, there were nearly 44 percent fewer HIV infections among participants who were assigned to take Truvada every day compared to those who took a placebo tablet. The study provided the first evidence that daily use of an ARV tablet is safe and can help reduce the risk of HIV infection. iPrEx was funded by the U.S. National Institutes of Health (NIH) and involved 2,499 men who have sex with men at 11 sites in Brazil, Ecuador, Peru, South Africa, Thailand and the U.S.

Ongoing PrEP Trials

- The **Partners PrEP Study** is testing both tenofovir and Truvada against a placebo in serodiscordant couples, in which one partner is HIV infected and the other is not. The study has completed enrollment of 4,700 couples in Kenya and Uganda and expects to report results early 2013. It is being conducted by a team led by University of Washington researchers and is funded by the Bill & Melinda Gates Foundation.
- **VOICE** – Vaginal and Oral Interventions to Control the Epidemic – is evaluating the safety and effectiveness of two different ARV-based approaches for preventing sexual transmission of HIV in women: daily use of an ARV tablet (tenofovir or Truvada) and daily use of an ARV-based vaginal gel (tenofovir gel). The study began in September 2009, and is fully enrolled with more than 5,000 women in Uganda, South Africa and Zimbabwe. Results, which are anticipated early 2013, will help determine not only the safety and effectiveness of each approach, but also which women prefer to use. The NIH-funded study is being conducted by the Microbicide Trials Network.
- The **Bangkok Tenofovir Study** is testing the effectiveness of tenofovir taken daily for reducing the risk of HIV among injection drug users in Thailand. Results of this trial, which is being conducted by the CDC, are anticipated in 2012.
- **iPrEx OLE** (r Open Label Extension) is a continuation of the iPrEx study designed to provide additional information about the safety of Truvada as PrEP and adherence to and other “real world” challenges of a daily regimen. iPrEx OLE is open to former iPrEx participants who remain HIV-negative. Those who enroll will receive Truvada for 72 weeks. The study is expected to be fully enrolled by late 2011.

Another trial, called **FEM-PrEP**, is closing earlier than originally planned following an interim review by its independent data monitoring committee in March 2011 that determined that even if the study were to continue, it would not be able to conclude whether or not Truvada is effective for prevention of HIV in its study population of high-risk women in Kenya, South Africa and Tanzania. The FHI researchers conducting the study plan to collect additional data before the study’s closure. A final report is expected to be available early 2012. FEM-PrEP was funded by the U.S. Agency for International Development (USAID), and received early support from the Bill & Melinda Gates Foundation.

#

More information about current, planned and completed trials can be found at [AVAC: Global Advocacy for HIV Prevention’s Pre -Exposure \(PrEP\) Trials Web page](#).

The [Microbicide Trials Network \(MTN\)](#) is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases 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 U.S. National Institutes of Health. More information about the MTN is available at www.mtnstopshiv.org.