



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

FACT SHEET

Tenofovir, Truvada and Tenofovir Gel: Products Being Tested in the VOICE Study

The VOICE Study – Vaginal and Oral Interventions to Control the Epidemic – is a major HIV prevention trial evaluating two different antiretroviral (ARV)-based approaches for preventing sexual transmission of HIV in women. Also known as MTN-003, the VOICE Study is testing the safety and effectiveness of these HIV prevention approaches as well as trying to determine which women are more apt to follow: taking an ARV tablet by mouth once a day, an approach known as oral pre-exposure prophylaxis (PrEP); or applying a vaginal gel every day. The ARV tablets being tested in VOICE are called tenofovir (also known as Viread[®]) and Truvada[®]. The vaginal gel is an ARV-based candidate microbicide called tenofovir gel.

Fast Facts: The ARVs Tenofovir and Truvada

- Tenofovir and Truvada are oral drugs approved for the treatment of HIV. When used in combination with other ARVs as part of a regimen called antiretroviral therapy (ART), they are very effective for improving the health of people with HIV. ART is considered the standard approach for treating HIV.
- Although these tablets have been used successfully as part of ART for the treatment for people with HIV, it is not known if they work to protect people from getting HIV in the first place. Other trials, in addition to VOICE, also are testing tenofovir and Truvada to see if either or both are effective for preventing people from getting infected if they are exposed to HIV, such as through sexual intercourse.
- Both drugs belong to a class of ARVs called nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), which act against HIV by targeting a key enzyme the virus needs to make a copy of its genetic material – an essential step for the virus to multiply and infect other cells inside the body.
- The full name for tenofovir is tenofovir disoproxil fumarate (TDF). It is also known by the brand name Viread.
- Truvada is the brand name for a combination drug that contains tenofovir and another active ingredient called emtricitabine (FTC). Sometimes researchers refer to Truvada as TDF+FTC.
- Participants in VOICE are given the same daily doses of tenofovir and Truvada used for treating HIV. Tenofovir is a 300-mg tablet. A single Truvada tablet contains 300 mg of tenofovir and 200 mg of FTC.
- Both drugs are usually safe and cause few side effects when they are used as part of ART in HIV-infected people. Occasional minor side effects can be upset stomach, dizziness, headache, joint pain or fever. Serious side effects are rare, but can include liver function problems, kidney damage or failure, or reduction in bone mineral density.
- Much less is known about the safety and side effects of these drugs in people without HIV, so VOICE researchers are monitoring study participants very closely. Of note are results of a study conducted by Family Health International in HIV-negative women in Ghana, Cameroon and Nigeria that found no serious side effects, including to the liver, kidney or bone, associated with daily use of tenofovir; some of the 859 participants studied for safety noted stomach discomfort and headache.

- more -

Fast Facts: Tenofovir Gel

- Microbicides are substances designed to prevent or reduce the sexual transmission of HIV when applied topically on the inside of the vagina or rectum.
- As a vaginal gel, tenofovir is among a newer class of candidate microbicides with specific activity against HIV.
- Tenofovir gel has the same active ingredient as the oral tablet. In oral tablet form, tenofovir is approved as a treatment for HIV infection in combination with other drugs; whereas, tenofovir gel is an experimental approach being evaluated for its ability to prevent the sexual transmission of HIV. It is not a treatment for HIV and it is not approved for use outside of research studies.
- Tenofovir gel comes in pre-filled applicators, each containing about a spoonful of gel. In its current formulation, each dose of gel inserted into the vagina contains approximately 40 mg of active drug.
- Laboratory and animal studies have shown that tenofovir gel acts on certain cells of the vagina and cervix that are primary targets for HIV infection. Such studies provided support for Phase I safety studies in people. In one study called HPTN 050 researchers found it was well tolerated by both HIV-negative and HIV-positive women who applied it up to two times a day for two weeks. Another study found no side effects in men when tenofovir gel was applied to the genital area daily. In 2008, researchers reported results from an expanded safety and acceptability trial called HPTN 059 that found daily use of the gel over six months by sexually active HIV-negative women safe and well-tolerated.
- Side effects experienced by women in previous trials of tenofovir gel were minor and included dryness, itching, burning or discomfort in the genital area. All participants in VOICE are closely monitored for side effects and safety by investigators throughout the trial.
- Another Phase IIb study called CAPRISA 004 found tenofovir gel reduced the risk of HIV by 39 percent among women who used it before and after vaginal sex compared to women who used a placebo gel. CAPRISA 004 was conducted in South Africa and involved 889 women. Other studies are being planned to confirm these results with the same dosing regimen.

Who Makes Tenofovir, Truvada and Tenofovir Gel?

Tenofovir, Truvada and tenofovir gel all were developed by Gilead Sciences, Inc., of Foster City, California, USA, which assigned a royalty-free license for the topical gel to the International Partnership for Microbicides of Silver Spring, Maryland, and CONRAD, of Arlington, Virginia, in December 2006. For VOICE, Gilead is providing tenofovir and Truvada tablets free of charge, and CONRAD is providing both the gel and gel applicators at no cost.

#

The VOICE Study is being conducted by a team of researchers working in the Microbicide Trials Network (MTN), an HIV/AIDS clinical trials network established and funded in 2006 by the National Institute of Allergy and Infectious Diseases (NIAID) with co-funding from the National Institute of Mental Health and the Eunice Kennedy Shriver National Institute of Child Health and Human Development, all components of the U.S. National Institutes of Health (NIH). Additional information about the VOICE Study can be found at <http://www.mtnstopshiv.org/news/studies/mtn003>

27-Sept.-2010