

The iPrEx clinical trial reported results of one drug being studied for a new approach to HIV prevention, called pre-exposure prophylaxis, or PrEP. The trial looked at whether a once-daily pill containing tenofovir (TDF) and emtricitabine (FTC) was safe and effective at reducing HIV risk in HIV-negative gay and bisexual men and transgender women, when used in combination with other proven HIV prevention methods like condoms. The TDF/FTC pill (brand name Truvada) is already licensed for use as HIV treatment. This study was conducted in Brazil, Ecuador, Peru, South Africa, Thailand and the US with 2,499 HIV-negative participants.

The results, released on November 23, showed that TDF/FTC reduced risk of HIV infection by 43.8%. This is a statistically significant result. It is the first proof that daily oral use of an ARV can reduce HIV risk and is an important step for HIV prevention.

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- **In iPrEx, daily TDF/FTC helped prevent HIV among HIV-negative gay and bisexual men when used with condoms and other HIV prevention methods.** The observed benefit was seen among participants who also received monthly HIV testing, counseling, condoms, treatment for sexually transmitted infections and other services.
 - **iPrEx evaluated one particular HIV drug as PrEP.** This pill contains a combination of two drugs, TDF/FTC. Other HIV drugs are being considered for oral PrEP, but there are no data on other oral agents.
 - **PrEP is not yet recommended for use.** iPrEx tested TDF/FTC for PrEP under specific research conditions. More information is needed to translate the trial finding into “real world” programs for gay men. Given that iPrEx tested an already licensed drug, there is the potential for immediate, off-label use. In the US, the Centers for Disease Control and Prevention issued interim guidance on PrEP as an HIV prevention strategy for MSM. It addresses key considerations for health care providers in the US considering daily oral TDF/FTC as PrEP for their MSM clients. Other national and international agencies have yet to provide any formal guidance.
 - **You can still get HIV when taking PrEP.** iPrEx found that PrEP using TDF/FTC is only partially effective. If approved for use as an HIV prevention strategy, it should be used with—not instead of—condoms, safer sex practices and other HIV prevention methods.
 - **PrEP is not a “vaccine” or a “morning-after” pill. The strategy as studied involves ongoing pill-taking.** In iPrEx, TDF/FTC was effective when participants received intensive counseling to take the drug every day. There is no evidence supporting the effectiveness of this PrEP drug in any other context. In the trial, participants who reported taking the TDF/FTC pill consistently had the highest levels of protection.
 - **PrEP is not for everyone at risk of HIV.** The iPrEx trial showed that the TDF/FTC pill was partially effective for some gay and bisexual men at high risk of HIV, who took the pill regularly, were counseled to reduce HIV risk behavior and were closely monitored. The iPrEx results cannot be extrapolated to other populations. Only other PrEP studies underway among heterosexual men and women and injecting drug users will tell us whether this or other PrEP strategies work in these other groups.

More information about key issues in the iPrEx study and the future of PrEP is available in AVAC’s PrEP and the iPrEx Trial FAQ is online at www.avac.org/iprex.