

HPTN 073

What is HPTN 073?

HPTN 073 is a demonstration study designed to see if Black men who have sex with men (BMSM) are willing to use Truvada®, a daily pill for pre-exposure prophylaxis (PrEP). HPTN 073 will gather feedback about the experience from the men who elect to use PrEP. PrEP is a new HIV prevention method in which people who are HIV-negative take an HIV treatment drug (antiretroviral – ARV) daily to reduce their risk of becoming HIV-infected.

HPTN 073 is coordinated by the HIV Prevention Trials Network (HPTN) and is sponsored and funded by the National Institute of Mental Health (NIMH) and National Institute of Drug Abuse (NIDA), divisions of the National Institutes of Health (NIH).

How does PrEP work?

The idea behind PrEP is that if an HIV-negative person takes certain ARV pills on a regular schedule before they are exposed to HIV through sex, they may be protected from HIV infection. The FDA approved daily oral Truvada® for PrEP in July, 2012. To date Truvada® is the only ARV approved by the FDA for HIV prevention in adults. Truvada® is currently available for doctors to prescribe for use as PrEP.



Truvada: File Photo

At least seven PrEP studies have either recently been completed, or are currently underway in a total of 13 countries involving over 20,000 people with diverse risk behaviors. In 2010, the iPrEx study published results that showed the daily use of oral Truvada® reduced the risk of HIV infection by 44% in HIV-negative men who have sex with men (MSM) and transgender women. The study found participants who had more Truvada® in their body were better protected than those who did not take the pills daily. In 2011, two additional studies also found Truvada® effective in reducing HIV infection among heterosexual men and women. Two different studies have shown that PrEP is not effective if it is not taken as prescribed. The VOICE study, which evaluated oral and topical PrEP, and Fem-PrEP, which evaluated oral use of Truvada® as PrEP, were both conducted with heterosexual women in Africa. Neither study showed that PrEP worked with those study participants because a majority of the participants did not take the drug as instructed.

What do we hope to learn from HPTN 073?

BMSM account for 28% of all new HIV infections in the U.S., yet BMSM are underrepresented in HIV research trials. Less than 50 of the 225 MSM who participated in the iPrEx study at the two U.S. sites were BMSM. To determine the effectiveness of PrEP in this population, researchers must first understand:

- How willing BMSM are to take PrEP
- How consistently the men who do decide to take PrEP, take it as prescribed
- How the men evaluate the experience of using PrEP, and
- Is it acceptable for local health care facilities to administer client-centered care coordination (C4) along with PrEP to BMSM

Who is participating in the study?

HPTN 073 will enroll a total of 225 HIV-negative BMSM in 3 U.S. cities: Chapel Hill, NC; Los Angeles, CA; and Washington, D.C. To enroll in the study participants must be at least 18 years old and able to provide written informed consent. HIV infection rates are highest among BMSM aged 18 to 25. As a result, this study will strive to enroll participants from that age group. The total duration of the study at each site is estimated to be less than two years.

What will happen during the study?

The ARV that will be used in HPTN 073 is Truvada®. Once study participants are enrolled in the study they will remain involved for about one year. Participants will meet with members of their local study team about seven times over the course of that year. At each of these visits the study team will offer participants the option to use Truvada®. During those visits a member of the study team will provide the participants who have started PrEP with a physical exam that includes checking the health of their liver and kidneys, and a discussion of any concerns or side effects that may be related to the study drug. Though it is not expected, if there are any serious side effects reported, study participants will be told to stop taking the drug.

Participants do not have to agree to take Truvada® to be in this study. They may decide to start taking or stop taking Truvada® at any time. Regardless of whether or not participants utilize Truvada®, everyone will be offered C4 assistance (client-centered care coordination). The C4 healthcare team will develop an individualized plan of care and support that may include referrals to health care and mental health services or to other organizations that can help participants with other needs they may have, such as services for housing assistance, domestic violence or drug or alcohol use counseling. All participants will receive HIV/sexually transmitted infection (STI) risk reduction counseling and an HIV/STI test at each study visit. All participants will be provided with condoms and will be encouraged to use condoms every time they have sex because, while previous studies have shown that Truvada® can reduce the risk of HIV infection, PrEP is not 100% effective and does not protect against other STIs (such as gonorrhea, syphilis or chlamydia).

What is HPTN?

The HIV Prevention Trials Network (HPTN) is a worldwide collaborative clinical trials network that brings together investigators, ethicists, community and other partners to develop and test the safety and efficacy of interventions designed to prevent the acquisition and transmission of HIV. HPTN studies evaluate new HIV prevention interventions and strategies in populations and geographical regions that bear a disproportionate burden of infection. HPTN receives its funding from three NIH institutes: the National Institute of Allergy and Infectious Diseases, the National Institute of Mental Health and the National Institute on Drug Abuse.

Where can I find more information about HPTN 073?

To learn more about HPTN 073 and the HIV Prevention Trials Network, visit www.hptn.org or follow us on Facebook: www.facebook.com/HIVptn or Twitter: www.twitter.com/HIVptn.

