HPTN
HIV Prevention
Trials Network

Prevention **NOW!**

HPTN 083 Frequently Asked Questions (FAQ)

1. **What is HPTN 083?**

   HPTN 083 is the first large-scale clinical trial of a long-acting injectable drug for HIV prevention. The study will examine whether a long-acting form of the anti-HIV drug cabotegravir (CAB) injected once every eight weeks can safely protect people from getting HIV infection at least as well as another anti-HIV medication combination taken as an oral tablet daily for HIV prevention, also known as pre-exposure prophylaxis (PrEP). The oral tablet, called Truvada, consists of the two anti-HIV drugs – emtricitabine and tenofovir disoproxil fumarate (TDF/FTC).

2. **Where will this study be done?**

   The study will take place at several sites in Argentina, Brazil, India, Peru, South Africa, Thailand, the United States and Vietnam.

3. **What organizations are involved with this study?**

   The HPTN 083 study is jointly funded by the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and ViiV Healthcare. Study drugs are provided by ViiV Healthcare and Gilead Sciences, Inc.

4. **Why is this study being done?**

   For people who are healthy and not infected with HIV, taking a daily pill can be challenging. The development of alternative agents for PrEP would increase prevention choices. Long-acting agents like cabotegravir have the potential to prevent HIV acquisition without relying on adherence to taking a daily pill. Some people also may find periodic injections to be a more discreet form of HIV prevention than daily pills and may prefer injectable cabotegravir for that reason.

5. **How many people will be in this study and who can participate?**

   The study will enroll 4,500 cisgender men who have sex with men (MSM) and transgender women (TGW) who have sex with men. Participants will be aged 18 years or older and at high risk for acquiring HIV infection.

6. **What will happen during the study?**

   HIV uninfected persons who are at increased risk of HIV acquisition will be assigned by chance to either CAB or TDF/FTC in a double blind manner. This means that neither the participant nor the staff will know what the person is receiving. Neither the participants nor the study team will know who is in which group until after the trial has completed. Participants will take either cabotegravir or TDF/FTC medications in the study, but will get an injection and oral tablets– one will be active and the other will be a placebo. The

study is designed in three steps: Step 1 is a five-week oral tablet phase to assess the safety of the study agents before proceeding to injections; Step 2 is the injection phase, where oral tablets are taken daily and injections are given at two time points four weeks apart followed by every eight weeks thereafter; and Step 3 is an open-label oral TDF/FTC phase, where all participants that are done receiving injections are given open-label oral TDF/FTC for up to a year. Study participants will be transitioned to locally-available HIV prevention services, which may include PrEP, when their participation in the study ends.

7. Will injectable cabotegravir be tested for HIV prevention in women as well?

Yes, a study called HPTN 084 will test the safety and efficacy of injectable cabotegravir for HIV prevention in women. The study will take place in sub-Saharan Africa and is expected to launch in 2017.

8. Is injectable cabotegravir safe?

Studies conducted so far in HIV infected and HIV uninfected people have shown it to be safe and tolerable. Some studies are still on-going and safety is continuing to be assessed. Safety will continue to be assessed in HPTN 083.

9. Can injectable cabotegravir protect participants from getting infected with HIV?

We do not know if injectable cabotegravir can protect people from getting HIV, and that is why we are conducting HPTN 083 and HPTN 084 to evaluate whether cabotegravir is as effective as oral TDF/FTC.

10. What HIV preventive care will study participants receive?

HPTN 083 study participants will receive HIV testing and prevention counseling, condoms and lubricant, as well as counseling to encourage and support adherence to the daily oral pill throughout the study. Participants who become HIV infected during the study will be referred to locally-available HIV treatment services. Participants also will receive sexually transmitted infection testing throughout the study and will be referred for treatment per local guidelines.

11. When are results expected?

Results are expected in 2021.

12. How is HPTN ensuring the safety of HPTN 083 study participants?

Multiple individuals and groups will carefully monitor the safety of HPTN 083 study participants. On a daily basis, the principal investigators at study sites will report and manage any adverse health outcomes, and the study team will monitor reports of safety data from the sites. In addition, a clinical management committee will assist principal investigators if unexpected safety concerns arise.

Furthermore, both a study monitoring committee and an independent data and safety monitoring board (DSMB) will conduct periodic reviews of participants' safety. A DSMB is composed of clinical research experts, statisticians, ethicists and community representatives who meet periodically during a study to review safety and efficacy data as it is gathered. A statistician who is not part of the study team presents mid-study data to the DSMB. The DSMB alerts the study team if anything appears to raise a new safety concern for study participants, if there is compelling evidence that the study intervention is effective, or if it becomes clear that the study cannot answer one of the questions it was designed to address. If indicated, the DSMB can advise that the study be ended early.

13. What will happen to study participants who acquire HIV infection during the trial?

Study participants who acquire HIV infection during the trial will stop receiving the study medications and will be immediately referred and facilitated to local medical providers for HIV care and treatment, including suppressive anti-HIV ART.

14. Where can I find more information?

For more information about HPTN 083, visit hptn.org, or ClinicalTrials.gov using study identifier NCT02720094.

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