The HIV Prevention Trials Network

HPTN 083 FAQ

1. What is HPTN 083?

HPTN 083 is the first study to compare the efficacy of CAB LA to daily oral TDF/FTC for HIV PrEP. HPTN 083 enrolled 4,570 cisgender men and transgender women (TGW) who have sex with men at 43 sites in Argentina, Brazil, Peru, United States, South Africa, Thailand and Vietnam.

Cabotegravir Injection

Truvada Tablet

2. Why was this study being done?

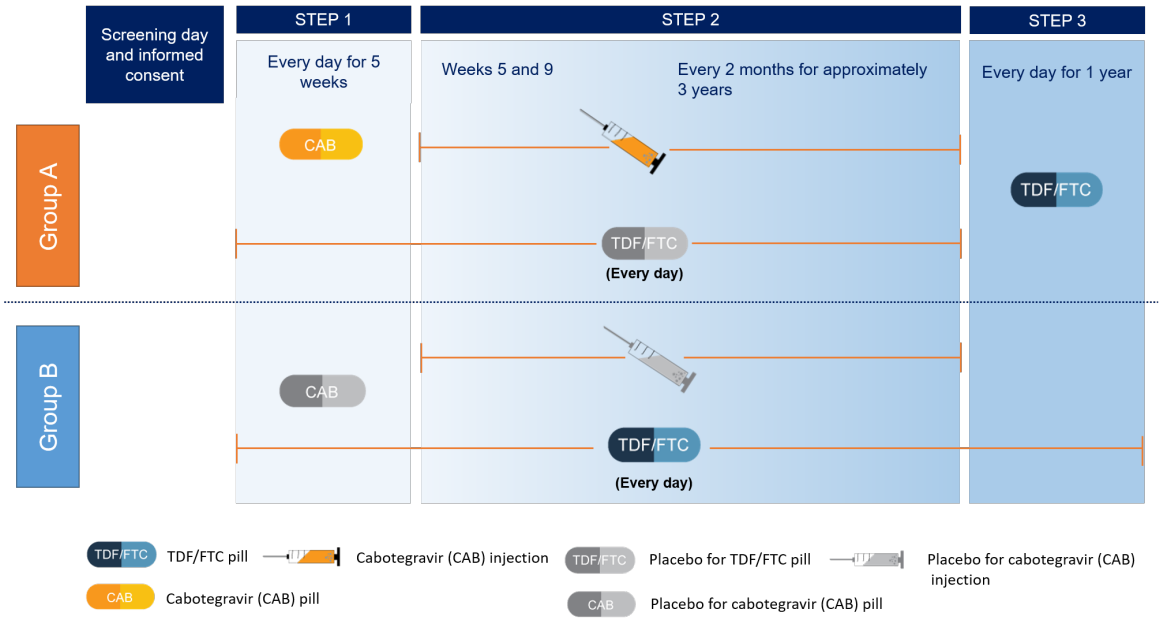
For many people, taking a daily pill can be challenging. The development of safe and effective long acting alternative agents for HIV PrEP would increase HIV prevention choices and help those who find taking a daily pill challenging. Some people also may find periodic injections to be a more discreet form of HIV PrEP than daily pills and may prefer CAB LA for that reason.

3. What organizations are involved in HPTN 083?

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. What happened during HPTN 083?

Participants were assigned randomly (by chance) to either the CAB or oral TDF/FTC group. Neither the participants nor the study team knew who was in which group. Participants in each group received both injections and oral tablets – each participant received one active drug and one placebo (no active drug) in order to maintain the blinded nature of the study. Participants were randomized to one of two study arms and included three steps: Step 1 consisted of 5 weeks of daily oral CAB and a TDF/FTC placebo or 5 weeks of daily oral TDF/FTC and an oral CAB placebo; Step 2 consisted of 148 weeks of intramuscular CAB LA 600 mg every 8 weeks plus daily oral TDF/FTC placebo or 148 weeks of daily oral TDF/FTC plus an intramuscular CAB LA placebo every 8 weeks ; and Step 3 consisted of an open-label daily oral TDF/FTC for 48 weeks after participants completed Step 2.



5. Why did the DSMB recommend stopping the blinded phase of the study?

On May 14, 2020, a Data and Safety Monitoring Board (DSMB) reviewed HPTN 083 study data and recommended that the blinded phase of the study be stopped early for successfully meeting its specified objectives. The study results showed that CAB LA, administered every eight weeks, provided high efficacy compared to TDF/FTC. A total of 50 incident HIV infections occurred in HPTN 083, with 38 incident HIV infections in the TDF/FTC arm (incidence rate 1.21%) and 12 incident HIV infections in the CAB arm (incidence rate 0.38%): in other words, approximately three times the number of incident HIV infections were in the TDF/FTC arm than in the CAB arm. The study sponsor, the U.S. National Institute of Allergy and Infectious Diseases (NIAID), approved the decision to stop the blinded part of the study.

6. Were the medications in the study deemed safe?

Overall, safety was similar between individuals receiving CAB LA and individuals receiving TDF/FTC tablets.

7. What will happen to the participants in HPTN 083 now?

Study participants will be informed of the study results and of which medication they were taking. Participants will be offered the opportunity to remain in the study, initially remaining on the active study medication that they were assigned to at the beginning of the study. Participants taking active TDF/FTC who wish to use CAB LA will be able to do so as soon as it is available. Participants who wish to may continue taking daily oral TDF/FTC.

8. Is injectable cabotegravir also being tested for HIV prevention among cisgender women?

Yes, a study called HPTN 084 is testing the safety and efficacy of injectable cabotegravir for HIV prevention among cisgender women. The study is taking place in sub-Saharan Africa and began in 2017. HPTN 084 was also reviewed by the DSMB and was recommended to continue.

9. Why did the DSMB make this recommendation for HPTN 083 and decide HPTN 084 will

HPTN 084 began enrollment in November 2017, about a year after HPTN 083 began enrollment. There was not enough data available from HPTN 084 to say if the study has reached its specified objectives. The DSMB will review data again from HPTN 084 later this year.

10. Did COVID-19 play a role in the recommendation of the DSMB?

Due to the potential for COVID-19 to significantly disrupt the conduct and data integrity of HPTN 083 going forward, the DSMB did consider the effects of COVID-19 on the future of the study. The data that the DSMB reviewed was almost entirely obtained prior to COVID-19-related disruptions at sites.

11. When will CAB LA be available for HIV PrEP?

It is too early to know when CAB LA may be available for the general public as the regulatory approval process requires several steps that need to occur first, including review and approval by the U.S. Food and Drug Administration and other regulatory agencies.