HPTN
HIV Prevention
Trials Network

Cabotegravir Studies

TAKING A DAILY PILL CAN BE CHALLENGING FOR MANY PEOPLE.

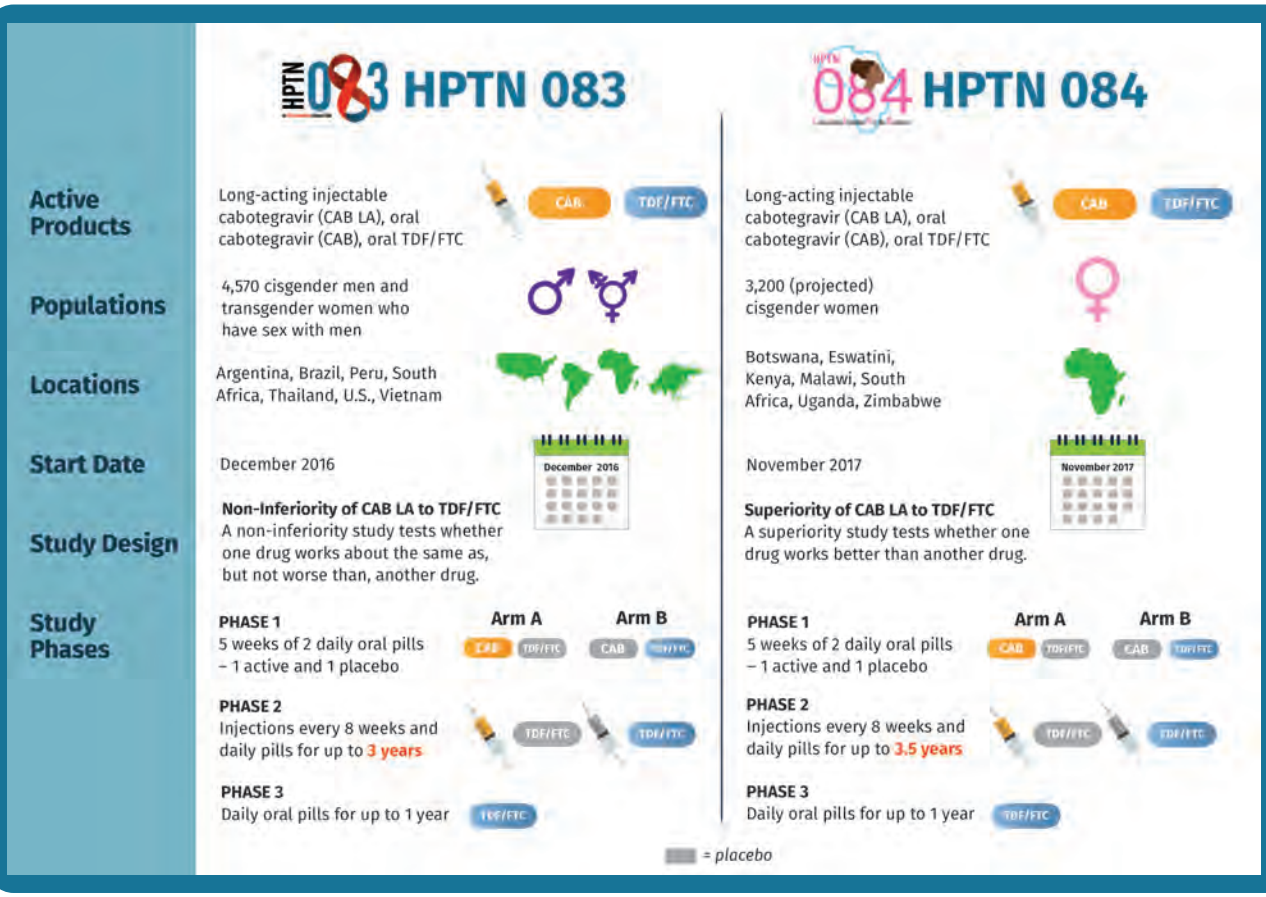
The development of safe and e¬ffective long-acting alternative agents for PrEP (pre-exposure prophylaxis) would increase HIV prevention choices and help those who find taking a daily pill challenging. The HPTN is studying long-acting injectable cabotegravir (CAB LA) for PrEP in woman and cisgender men who have sex with men, and adolescents.

HPTN 083

HPTN 083 is the first study to compare the efficacy of CAB LA to daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) for 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. The study results showed that CAB LA, administered every eight weeks, lowered HIV incidence among cisgender men and TGW who have sex with men.

HPTN 084

HPTN 084 (LIFE - **L**ong-acting **I**njectable **F**or the **E**pidemic) is the first study to compare the safety and efficacy of CAB LA to daily oral TDF/FTC for PrEP in cisgender women. HPTN 084 is enrolling about 3,200 cisgender women at 20 sites in Botswana, Kenya, Malawi, South Africa, Eswatini, Uganda and Zimbabwe.



HPTN 083 and HPTN 084 at a Glance

DATA AND SAFETY MONITORING BOARD REVIEW, MAY 2020:

On May 14, 2020, a Data and Safety Monitoring Board (DSMB) reviewed HPTN 083 and HPTN 084 study data. The DSMB, an independent group of experts that periodically reviews and evaluates study data for participant safety, study conduct and progress, and efficacy, recommended that the blinded phase of HPTN 083 be stopped early for successfully meeting its specified objectives. HPTN 083 results showed that CAB LA, administered every eight weeks, provided high efficacy compared to TDF/FTC among cisgender men and transgender women who have sex with men. 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.

The DSMB did not identify any safety concerns for cisgender women in HPTN 084 and recommended continuing the study as planned in order to accumulate enough data to answer the primary objective about the safety and efficacy of CAB LA among cisgender women.

HPTN 083 NEXT STEPS:

Study participants will be informed of which active medication they were taking, and the study findings. Participants will be offered the opportunity to remain in the study, initially taking only the active study medication they were randomized to. Participants initially randomized to active TDF/FTC who wish to switch to CAB LA will be able to do so as soon as enough CAB LA is available for all study participants. Those who wish to continue taking daily oral TDF/FTC will be allowed to do so until the end of the originally planned blinded study (up to 3 years after enrollment).

HPTN 084 NEXT STEPS:

The safety and efficacy of CAB LA may not be the same among cisgender women as it is among cisgender men and TGW. HPTN 084 (LIFE) will continue to be a rigorously conducted study and collect data about the safety and efficacy of CAB LA among cisgender women under the careful review of the study team and the DSMB. Results from HPTN 083 will be shared with HPTN 084 (LIFE) study participants, investigators, and regulators involved in the study. It is of utmost importance that the efficacy and the safety of CAB LA in women be as well understood as it is for cisgender men and transgender women. Cisgender women deserve HIV prevention options that have been proven to be safe and effective in cisgender women.

MORE INFORMATION:

HPTN 083 Study Website: GivePrEPaShot.Org
HPTN 084 Study Website: 084Life.org

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Cabotegravir Adolescent Studies

HPTN 083-01

HPTN 083-01 is examining whether CAB LA for PrEP is safe and acceptable in about 50 adolescents, including cisgender men who have sex with men, transgender women (TGW) and gender non-conforming people at sites in Boston; Chicago; and Memphis, TN. HPTN 083-01 is a sub-study of a larger clinical trial called HPTN 083.

HPTN 084-01

HPTN 084-01 (LIFT - **L**ong-acting **I**njectable **F**or **T**eens) is examining whether CAB LA for PrEP is safe and acceptable in about 50 cisgender adolescents at sites in South Africa, Uganda and Zimbabwe. HPTN 084-01 is a sub-study of a larger clinical trial called HPTN 084.

HPTN 083-01 and HPTN 084-01 at a Glance

	HPTN 083-01	HPTN 084-01
Active Products	Long-acting injectable cabotegravir (CAB LA), oral cabotegravir (CAB), oral TDF/FTC	Long-acting injectable cabotegravir (CAB LA), oral cabotegravir (CAB), oral TDF/FTC
Populations	About 50 adolescents assigned male at birth, including cisgender men who have sex with men, transgender women (TGW) and gender non-conforming people	About 50 cisgender adolescents assigned female at birth
Locations	**United States:** Boston, MA; Chicago, IL; Memphis, TN	**Africa:** South Africa, Uganda, Zimbabwe
Study Design	Single arm, open label study evaluating the safety, tolerability, and acceptability of CAB LA	Single arm, open label study evaluating the safety, tolerability, and acceptability of CAB LA
Study Phases	**PHASE 1** 5 weeks of daily oral pill **PHASE 2** Injections every 8 weeks for 29 weeks **PHASE 3** Daily oral pill for 48 weeks	**PHASE 1** 5 weeks of daily oral pill **PHASE 2** Injections every 8 weeks for 29 weeks **PHASE 3** Daily oral pill for 48 weeks