

Long-acting injectable cabotegravir highly effective at preventing HIV infection

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Microscopic image of an HIV-infected T cell. Credit: NIAID

The HIV Prevention Trials Network (HPTN) announced today results from [HPTN 083](#), a global randomized, controlled, double-blind study that compared the safety and efficacy of long-acting injectable

cabotegravir (CAB LA) to daily oral tenofovir/emtricitabine (TDF/FTC) (Truvada) for pre-exposure prophylaxis (PrEP). The study showed that CAB LA lowered HIV incidence among cisgender men and transgender women who have sex with men. During a planned review of study data, an independent Data and Safety Monitoring Board (DSMB) recommended that the study results be announced as soon as possible.

The study sponsor, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, agreed with this recommendation.

"Demonstrating conclusively that long-acting injectable cabotegravir is highly effective almost two years earlier than originally expected is exciting news," said HPTN 083 protocol chair Raphael J. Landovitz, MD, professor of medicine at the David Geffen School of Medicine at the University of California, Los Angeles and associate director of the UCLA Center for Clinical AIDS Research & Education (CARE). "It is inspiring that we may soon have additional HIV prevention options for at-risk individuals who have difficulty with or prefer not to take pills. We are indebted to our study participants and clinical research sites."

Overall, HPTN 083 enrolled 4,570 cisgender men and [transgender women](#) who have sex with men in Argentina, Brazil, Peru, Thailand, the U.S., Vietnam, and South Africa. Two-thirds of study participants were under 30 years of age, and 12% were transgender women. Half of the participants in the United States identified as Black or African American. A total of 50 incident HIV infections occurred in HPTN 083, with 38 incident infections in the TDF/FTC arm (incidence rate 1.21%) and 12 incident 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 hazard ratio in the CAB versus TDF/FTC arms is 0.31 (nominal 95% CI 0.16-0.59). These results demonstrate that CAB LA is highly effective

for the prevention of HIV acquisition in cisgender men and transgender women.

"A long-acting injectable for PrEP that does not require adherence to an oral daily pill is a great addition to the HIV prevention toolbox," said HPTN 083 protocol co-chair Beatriz Grinsztejn, MD, Ph.D., director of the Instituto de Pesquisa Clinica Evandro Chagas HIV/AIDS Clinical Research Centre of the Oswaldo Cruz Foundation-Fiocruz in Rio de Janeiro, Brazil. "Prevention strategies have never been one-size-fits-all."

Based on the recommendation by the DSMB, the blinded, randomized portion of the study will end. All participants will be informed of these results as soon as possible and will be told which study medication they received. Participants who were in the TDF/FTC arm will be offered CAB LA when it becomes available. Participants in the CAB LA arm will continue to receive it. Participants who do not want to receive CAB LA will be offered TDF/FTC.

"Until we have a safe and effective vaccine for HIV, we must continue to find innovative prevention strategies," said Myron Cohen, MD, HPTN co-principal investigator and director of the Institute for Global Health and Infectious Diseases at the University of North Carolina in Chapel Hill. "Increasing the number of effective tools will give people who want to prevent HIV an opportunity to find a method that works for them."

A companion study that began a year after, [HPTN 084](#), is comparing the efficacy and safety of CAB LA to daily oral TDF/FTC for PrEP among women in sub-Saharan Africa. This study, which began approximately a year after HPTN 083, was also reviewed by the DSMB and was recommended to continue as planned.

"The findings from HPTN 083 are an important milestone along the path towards ending the HIV epidemic," said Wafaa El-Sadr, MD, MPH,

HPTN co-principal investigator, director of ICAP and professor of epidemiology and medicine at Columbia University in New York. "We look forward to the results from HPTN 084, a critically important sister study among women at risk for HIV in sub-Saharan Africa."

More information: HPTN 083: A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men:

www.hptn.org/research/studies/hptn083

Provided by University of North Carolina at Chapel Hill School of Medicine

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