

HPTN 084



What is HPTN 084?

HPTN 084 (LIFE) is the first study to test whether an injection of cabotegravir (CAB) given once every two months works better than a Truvada pill taken every day for HIV prevention in women.



Cabotegravir Injection



Truvada Tablet

Who is participating in the study?

HPTN 084 will take place in Botswana, Kenya, Malawi, South Africa, Swaziland, Uganda and Zimbabwe. The study will enroll about 3,200 women who are HIV uninfected. Women who join the study must be 18-45 years old.

What do we hope to learn from HPTN 084?

Women in sub-Saharan Africa are at risk for HIV and new effective methods of HIV prevention are needed. A Truvada pill taken every day containing two drugs, TDF and FTC (TDF/FTC), is currently recommended by the World Health Organization (WHO) for use as PrEP (pre-exposure prophylaxis: the use of medication to prevent infection) for people at risk for HIV infection. Several countries have approved TDF/FTC for use as PrEP.

Taking a daily pill for PrEP can be an effective tool for preventing HIV, but remembering to take a pill every day can be hard for some people. Newer, safe PrEP products that do not need to be taken every day are needed for people who may find it difficult or not want to take a pill every day.

In HPTN 084, researchers hope to learn whether an injection of CAB given once every two months is safe and works better than a Truvada pill taken every day in women. Researchers also hope to understand what women think about receiving CAB injections and taking Truvada pills for PrEP.

What will happen during the study?

Women who enroll in the study will be assigned at random (like flipping a coin) to either Group A or Group B. Each woman in each group will get an injection in the buttock every two months and a daily pill.

Women in both groups will get the same number of pills and the same number of injections. Group A will get CAB pills and CAB injections plus placebo Truvada pills (pills that look like Truvada pills, but have no active drug). Group B will get Truvada pills and placebo CAB pills (pills that look like CAB pills, but have no active drug) and placebo CAB injections (injections that look like CAB injections, but have no active drug). Both groups go through three steps in the study and some participants could be in the study for up to 4.5 years.

Group A

This group gets CAB pills and CAB injections plus Truvada placebo pills.

Step 1: Truvada pill plus a placebo CAB pill every day for five weeks

Step 2: Truvada pill every day plus one singular placebo CAB injection initially, then another placebo injection a month later, and then every two months after that up to three and a half years

Step 3: Truvada pill every day for about a year, then referred to local HIV prevention services, which may include PrEP.

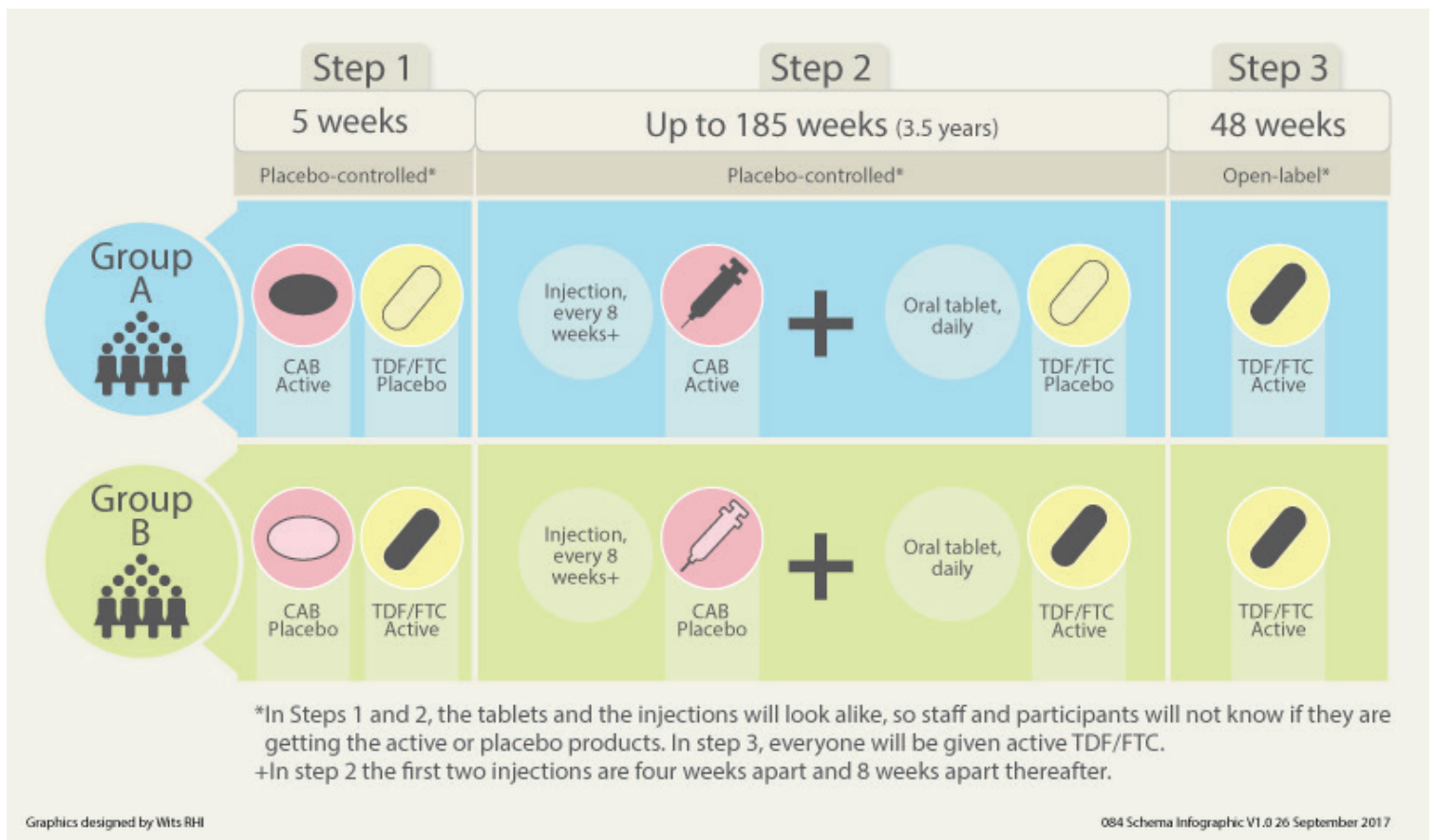
Group B

This group gets Truvada pills plus placebo CAB pills and placebo CAB injections.

Step 1: CAB pill plus a placebo Truvada pill every day for five weeks

Step 2: One singular CAB injection initially, then another injection a month later, and then every two months after that up to three and half years plus a Truvada placebo pill every day

Step 3: Truvada pill every day for about a year, then referred to local HIV prevention services, which may include PrEP.



Where can I find out more information about HPTN 084?

For more information please visit www.084LIFE.org.

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. The HPTN research agenda is focused primarily on the use of integrated strategies: use of antiretroviral drugs (antiretroviral therapy and pre-exposure prophylaxis); interventions for substance abuse, particularly injection drug use; behavioral risk reduction interventions and structural interventions. NIH funds HPTN. For more information, visit hptn.org.