

HPTN 083 HPTN 083

an HIV prevention clinical trial

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Long-acting Injectable For the Epidemic

Active Products

Long-acting injectable cabotegravir (CAB LA), oral cabotegravir (CAB), oral TDF/FTC



CAB

TDF/FTC

Populations

4,570 cisgender men and transgender women who have sex with men



Locations

Argentina, Brazil, Peru, South Africa, Thailand, U.S., Vietnam



Start Date

December 2016



Study Design

Non-Inferiority of CAB LA to TDF/FTC

A non-inferiority study tests whether one drug works about the same as, but not worse than, another drug.

Study Phases

PHASE 1

5 weeks of 2 daily oral pills – 1 active and 1 placebo

Arm A

CAB TDF/FTC

Arm B

CAB TDF/FTC

PHASE 2

Injections every 8 weeks and daily pills for up to **3 years**



TDF/FTC



TDF/FTC

PHASE 3

Daily oral pills for up to 1 year

TDF/FTC

Long-acting injectable cabotegravir (CAB LA), oral cabotegravir (CAB), oral TDF/FTC



CAB

TDF/FTC

3,200 (projected) cisgender women



Botswana, Eswatini, Kenya, Malawi, South Africa, Uganda, Zimbabwe



November 2017



Superiority of CAB LA to TDF/FTC

A superiority study tests whether one drug works better than another drug.

PHASE 1

5 weeks of 2 daily oral pills – 1 active and 1 placebo

Arm A

CAB TDF/FTC

Arm B

CAB TDF/FTC

PHASE 2

Injections every 8 weeks and daily pills for up to **3.5 years**



TDF/FTC



TDF/FTC

PHASE 3

Daily oral pills for up to 1 year

TDF/FTC

■ = placebo