



# Long-Acting Cabotegravir PrEP Is Safe During Pregnancy

Data from the HPTN 084 trial show injectable Apretude for PrEP was generally safe and well-tolerated for both pregnant women and babies.

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[At the International AIDS Conference], [HPTN 084](#) researchers presented new safety and pharmacokinetic (PK) findings for long-acting injectable cabotegravir (CAB-LA) [Apretude] when used before and during pregnancy. The findings show that CAB-LA used as pre-exposure prophylaxis (PrEP) was generally well tolerated and generally safe for both pregnant cisgender women and their babies. In addition, PK findings suggest that no dose changes are needed when using CAB-LA during pregnancy. To date, none of the women who became pregnant and continued to receive CAB acquired HIV during pregnancy.

In 2022, eligible HPTN 084 study participants were offered the choice of open-label CAB-LA or oral tenofovir/emtricitabine (TDF/FTC) for PrEP in the ongoing open-label extension (OLE) stage of the HPTN 084 study. Participants were not required to use a contraceptive for this part of the trial. Participants who took CAB-LA either before the pregnancy or during the pregnancy could choose to keep taking CAB-LA throughout pregnancy. Findings indicate that CAB-LA use before and during pregnancy was safe for the women and their babies.

The HPTN 084 OLE PK sub-study evaluated 50 participants who took CAB-LA for PrEP before and during pregnancy. The sub-study found that while CAB-LA concentrations among participants declined over the three pregnancy trimesters, drug levels remained above protocol-specified target levels. These PK findings suggest that no dose changes are required for pregnant cisgender women, but additional analyses are needed.

## About HPTN 084

HPTN 084 is an ongoing Phase 3 study of CAB-LA compared to TDF/FTC in individuals assigned female at birth in Eastern and Southern Africa. CAB-LA was previously demonstrated to be superior to oral TDF/FTC in preventing the acquisition of HIV infection. HPTN 084 continues as an OLE. Over 2400 participants from Botswana, Kenya, Malawi, South Africa, Uganda, Eswatini, and Zimbabwe are included in the OLE.

HPTN 084 is co-funded by the National Institutes of Health's (NIH) National Institute of Allergy and

Infectious Diseases, the Bill & Melinda Gates Foundation, and ViiV Healthcare. ViiV Healthcare and Gilead Sciences, Inc. provided the study product. Three other NIH institutes also collaborated on HPTN 084: the National Institute of Mental Health, the National Institute on Drug Abuse, and the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

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