

Biktarvy Is Safe and Effective During Pregnancy

Drug levels remained adequate throughout pregnancy, so no dose adjustment was needed.

August 16, 2023 By [Liz Highleyman](#)

The widely used single-tablet regimen Biktarvy (bictegravir/tenofovir alafenamide/emtricitabine) is safe, well tolerated and maintains viral suppression during pregnancy, according to study findings presented at the [International AIDS Society Conference on HIV Science](#) (#IAS2023).

[Biktarvy](#) is a recommended first-line regimen and switch option for adults living with HIV, but, like other newer antiretroviral regimens, it has not been extensively studied in pregnant women. Starting and staying on effective antiretroviral therapy during [pregnancy](#) not only improves the health of the mother, it also prevents HIV transmission to the baby.

Dhananjay Marathe, PhD, of Gilead Sciences, and colleagues conducted a study ([NCT03960645](#)) to evaluate the pharmacokinetics, safety and efficacy of Biktarvy in women who switch to the single-tablet regimen during pregnancy.

Bictegravir is highly protein bound and is metabolized by two enzymes, CYP3A4 and UGT1A1, that show increased activity during pregnancy, so drug concentrations could potentially fall to lower levels in pregnant people, the researchers noted as background.

This analysis included 33 HIV-positive pregnant women with stable viral suppression for at least six months who started Biktarvy during their second or third trimester. The researchers collected blood plasma samples over 24 hours following oral administration of Biktarvy during pregnancy and at six and 12 weeks after delivery. Drug levels were also measured in their newborns.

Overall, bictegravir concentrations were lower during pregnancy compared with postpartum, but median trough levels (the lowest level between doses) remained about six times higher than the amount needed to inhibit HIV replication. Of note, the one woman with an unusually low bictegravir level during pregnancy was taking calcium and iron supplements.

Levels of tenofovir alafenamide and emtricitabine were also somewhat lower, similar to those seen in previous studies that assessed these drugs used in other regimens during pregnancy. Trough levels of tenofovir diphosphate (the active form of the drug) in peripheral blood cells were

comparable during pregnancy and after delivery.

All the women maintained an undetectable viral load (below 50 copies) at the time of delivery and at the final postpartum assessment, and there were no cases of virological treatment failure. What's more, none of the newborns had a detectable viral load. Only one adverse event (false labor) was possibly linked to Biktarvy, no one stopped treatment due to adverse events and no infants experienced side effects.

“Despite the comparatively lower exposure to bictegravir, emtricitabine and TAF during pregnancy versus postpartum, all adult participants maintained virologic suppression,” the researchers concluded. “[Biktarvy] was generally well tolerated, suggesting appropriateness for use of [Biktarvy] during pregnancy and indicating that no dose change is needed.”

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