

# Valacyclovir on markers of disease progression in postpartum women co-infected with HIV-1 and herpes simplex virus-2.

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## Abstract

### OBJECTIVE:

Herpes simplex virus type 2 (HSV-2) suppression has been shown to reduce HIV-1 disease progression in non-pregnant women and men, but effects on pregnant and postpartum women have not been described.

### METHODS:

We analyzed data from a cohort of Kenyan women participating in a randomized clinical trial of HSV-2 suppression. Pregnant HIV-1-seropositive, HSV-2-seropositive women who were not eligible for antiretroviral therapy (WHO stage 1-2, CD4 > 250 cells/ $\mu$ l) were randomized to either 500 mg valacyclovir or placebo twice daily from 34 weeks gestation through 12 months postpartum. Women received zidovudine and single-dose nevirapine for prevention of mother-to-child HIV-1 transmission. HIV-1 progression markers, including CD4 count and plasma HIV-1 RNA levels, were measured serially. Multivariate linear regression was used to compare progression markers between study arms.

**RESULTS:** Of 148 women randomized, 136 (92%) completed 12 months of postpartum follow-up. While adjusted mean CD4 count at 12 months (565 cells/ $\mu$ l placebo arm, 638 cells/ $\mu$ l valacyclovir arm) increased from antenatal levels in both arms, the mean CD4 count increase was 73 cells/ $\mu$ l higher in the valacyclovir arm than placebo arm ( $p=0.03$ ). Mean increase in CD4 count was 154 cells/ $\mu$ l in the valacyclovir arm, almost double the increase of 78 cells/ $\mu$ l in the placebo arm. At 12 months, adjusted HIV-1 RNA levels in the placebo arm increased by 0.66 log(10) copies/ml from baseline, and increased by only 0.21 log(10) copies/ml in the valacyclovir arm (0.40 log(10) copies/ml difference,  $p=0.001$ ).

**CONCLUSION:** Women randomized to valacyclovir suppressive therapy during pregnancy and postpartum had greater increases in CD4 counts and smaller increases in plasma HIV-1 RNA levels than women in the placebo arm. Valacyclovir suppression during pregnancy and breastfeeding may improve outcomes and delay antiretroviral therapy for HIV-1/HSV-2 co-infected women.