Abstract

BACKGROUND:

We evaluated the efficacy of a maternal triple-drug antiretroviral regimen or infant nevirapine prophylaxis for 28 weeks during breast-feeding to reduce postnatal transmission of human immunodeficiency virus type 1 (HIV-1) in Malawi.

METHODS:

We randomly assigned 2369 HIV-1-positive, breast-feeding mothers with a CD4+ lymphocyte count of at least 250 cells per cubic millimeter and their infants to receive a maternal antiretroviral regimen, infant nevirapine, or no extended postnatal antiretroviral regimen (control group). All mothers and infants received perinatal prophylaxis with single-dose nevirapine and 1 week of zidovudine plus lamivudine. We used the Kaplan-Meier method to estimate the cumulative risk of HIV-1 transmission or death by 28 weeks among infants who were HIV-1-negative 2 weeks after birth. Rates were compared with the use of the log-rank test.

RESULTS:

Among mother-infant pairs, 5.0% of infants were HIV-1-positive at 2 weeks of life. The estimated risk of HIV-1 transmission between 2 and 28 weeks was higher in the control group (5.7%) than in either the maternal-regimen group (2.9%, P=0.009) or the infant-regimen group (1.7%, P<0.001). The estimated risk of infant HIV-1 infection or death between 2 and 28 weeks was 7.0% in the control group, 4.1% in the maternal-regimen group (P=0.02), and 2.6% in the infant-regimen group (P<0.001). The proportion of women with neutropenia was higher among those receiving the antiretroviral regimen (6.2%) than among those in either the nevirapine group (2.6%) or the control group (2.3%). Among infants receiving nevirapine, 1.9% had a hypersensitivity reaction.

CONCLUSIONS:

The use of either a maternal antiretroviral regimen or infant nevirapine for 28 weeks was effective in reducing HIV-1 transmission during breast-feeding. (ClinicalTrials.gov number, NCT00164736.)