Maternal Triple Antiretrovirals (mART) and Infant Nevirapine (iNVP) Prophylaxis for the Prevention of Mother-to-Child Transmission (MTCT) of HIV during Breastfeeding (BF)

BACKGROUND

Breastfeeding (BF) is crucial to reducing infant morbidity and mortality in developing countries but may result in HIV transmission if the mother is HIV-infected. Prior clinical trials showed that both maternal antiretroviral treatment (mART) and infant nevirapine (iNVP) are effective in prevention of perinatal transmission of HIV. PROMISE is the first randomized trial that designed to directly compare the efficacy and safety of these two strategies during extended BF into the second year of life. PROMISE studies involved three randomizations: antiretroviral, postpartum, and breastfeeding, and maternal health following breastfeeding, as shown below.

RESULTS

WOMEN WERE ASYMPTOMATIC

Women were asymptomatic with median CD4+ cell count of 868 cells/mm³ and 97% WHO Clinical Stage 1. Women had a median age of 25 years.

INFANT CHARACTERISTICS

Infant’s median gestational age and birthweight were 39 weeks and 2.9 kg, respectively.

OTHER BASELINE CHARACTERISTICS

Baseline characteristics were comparable by study arm. Median duration of breastfeeding was 15 months and not significantly different by study arm (p=0.88). Kaplan-Meier estimates of perinatal transmission of HIV are shown in Figure 2-3 below; there were no statistically significant differences between the two arms. Infant 12-month survival rate was extremely high (98.9%) and did not differ significantly by arm (Figures 4 & 5). Incidence rates of maternal and infant safety outcomes did not differ significantly by regimen (Table 1).

CONCLUSIONS

Both maternal ART and infant iNVP were safe, associated with very low postnatal transmission rates during extended breastfeeding and infant high survival rates. For mothers who either do not adhere to or tolerate ART, daily infant iNVP throughout breastfeeding offers a safe and effective PMTCT alternative during breastfeeding.

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