

# AIDS BRIEFS

## LITTLE DIFFERENCE IN HIV TRANSMISSION RATES BETWEEN FORMULA-FED INFANTS AND THOSE BREAST-FED WHILE MOTHERS TAKE AZT

The use of prophylaxis in babies breast-fed by HIV-positive mothers can reduce HIV transmission to comparable rates to formula-fed babies, according to a study presented at the recent Twelfth Annual Conference on Retroviruses in Boston. However, there is a risk of the baby developing at least temporary resistance to the drugs used.

A Botswana trial in which various combinations of zidovudine (AZT), lamivudine (3TC) and nevirapine were shown to reduce mother-to-child transmission of HIV to 4% was continued to a second phase, in which babies were randomised to receive either formula feed, or breast-fed and given AZT until 7 months of age. All the babies were given AZT until they were 1 month old. By the age of 18 months, 14% of formula-fed and 16% of breast-fed babies were HIV-positive (including those who were HIV-positive at birth). However, at 7 months, when AZT was stopped, there was a larger difference, with 6% of formula-fed babies HIV-positive, and 9% of those who were breastfed and given AZT. However, the formula-fed babies had higher mortality rates overall; 9% died by 8 months compared with 5% of breast-fed babies. But, by 18 months mortality rates were similar.

An encouraging finding in this trial was that mothers were relatively adherent to formula feeding, with only 9% saying that they had sometimes breast-fed, despite overall poor socioeconomic conditions that included lack of access to safe water and to electricity. In contrast, only 18% of the women who were breast-feeding did so exclusively up to 18 months, and only 50% up to 7 months.

A Ugandan study in which children were given either nevirapine or 3TC prophylaxis while breast-feeding found that 92% of the 13 children receiving nevirapine developed resistance and 69% of those taking 3TC. However, this resistance faded over time, with only 2 of the infants having a detectable mutation 3 - 6 months later.

Thior I, *et al.* Twelfth Conference on Retroviruses and Opportunistic Infections, Boston, 2005 Abstract 75LB.  
Giuliano M, *et al.* Twelfth Conference on Retroviruses and Opportunistic Infections, Boston, 2005 Abstract 99.

## THREE TRIALS BRING MOTHER-TO-CHILD TRANSMISSION OF HIV DOWN TO 4%

Three trials of different regimens of nevirapine plus nucleoside reverse transcriptase inhibitors (NRTIs) to prevent vertical transmission of HIV have brought the transmission rate down to below 5%, according to presenters at the recent Twelfth Conference on Retroviruses and Opportunistic Infections, Boston. This is the lowest vertical transmission rate so far seen in Africa.

### DREAM study

This trial in Mozambique used nevirapine plus either AZT/3TC or stavudine (d4T)/3TC from the 25th week of pregnancy or 60 days pre-delivery to 6 months post-delivery; a total of 778 women completed the protocol. The babies were not given antiretrovirals. The overall transmission rate at birth was 4.1%. However, there was a large disparity between the AZT and d4T regimens – the transmission rates achieved were 3.7% and 11.1%, respectively. During the first month, 1.4% of babies were infected during breast-feeding and 0.6% after that, leading to an overall transmission rate of 6.1%.

### DITRAME+ study

This trial in Côte d'Ivoire offered 329 women AZT and 3TC from 32 weeks of pregnancy to 3 days after giving birth. During labour they had a single dose of nevirapine and an extra dose of AZT/3TC. The babies received AZT for 7 days after birth and a single dose of nevirapine 2 days postpartum.

At 6 weeks, the transmission rate was 4.7%; viral load in the women who transmitted the virus was higher than in women who did not.

### MASHI study

The Botswana MASHI study was a randomised placebo-controlled trial giving AZT and nevirapine in various combinations to mothers and babies, combined with breast-feeding interventions. During the first study period there were 485 births with a transmission rate at birth of 3.7% to babies given nevirapine and 4.5% to babies given placebo. The protocol was revised in the light of these results, with the nevirapine placebo arm judged unethical, and all babies were subsequently given nevirapine as soon as possible after birth and half the mothers received placebo. During the second study period there were 694 births; the transmission rates at birth were 2.3% for mother/baby

pairs who both received nevirapine and 3.8% where the mother received a placebo. In both cases transmission rose in the months after birth. During the second study period, the women had access to highly active antiretroviral therapy and 71 of the 694 women took it.

The overall transmission rate at birth in the entire study was 4%.

Chaix M, *et al.* Twelfth Conference on Retroviruses and Opportunistic Infections, Boston, 2005 Abstract 72LB.  
Palombi L, *et al.* Twelfth Conference on Retroviruses and Opportunistic Infections, Boston, 2005 Abstract 67.  
Shapiro R, *et al.* Twelfth Conference on Retroviruses and Opportunistic Infections, Boston, 2005 Abstract 74LB.

## SINGLE-DOSE NEVIRAPINE REDUCES HIV TRANSMISSION IN SECOND PREGNANCIES

HIV-positive women who have previously used single-dose nevirapine to prevent vertical transmission can use the same drug to prevent transmission in a second delivery, according to a pilot study presented at the recent Twelfth Conference on Retroviruses and Opportunistic Infections, Boston.

Researchers in Soweto looked at 106 women using nevirapine for a second pregnancy. A further 212 women using nevirapine for the first time were also recruited into the study as controls. Maternal viral load, CD4 cell count and resistance profile were determined at baseline and at 6 weeks after delivery. HIV infection in the babies was determined using PCR testing at 6 weeks. Babies of the women using nevirapine in their second pregnancy were more likely to be infected with HIV 6 weeks after delivery than those of women using nevirapine for their first pregnancy, although the difference was not statistically significant. Investigators concluded from this that using nevirapine for a second time is still an effective way of preventing vertical transmission.

Researchers called for further investigation into the use of nevirapine for more than one pregnancy as a matter of urgency as more women will be using the drug for subsequent pregnancies.

Martinson N, *et al.* Twelfth Conference on Retroviruses and Opportunistic Infections, Boston, 2005 Abstract 103.

## PREGNANT WOMEN WITH HIGHER CD4 CELL COUNTS NOT AT GREATER RISK OF NEVIRAPINE-RELATED TOXICITY

A study in Kenya has shown that pregnant women with relatively high CD4 cell counts showed a similar incidence of liver toxicity and serious allergic reactions to those seen in other nevirapine trials. Studies in North America, Europe and South Africa have shown that women with CD4 counts of more than 250 cells/ $\mu$ l are at greater risk of serious side-effects than women with more advanced disease, leading to guidelines recommending that nevirapine must be avoided in this population.

However, in the Kisumu study in Kenya, 155 women were included in an analysis of the toxicity of various drug combinations, including nevirapine combined with AZT and 3TC. This combination is taken from 34 weeks of gestation and during breast-feeding to prevent vertical transmission of HIV. At baseline, the women's mean CD4 cell count was 458 cells/ $\mu$ l. To date, there have been 13 serious adverse events leading to the discontinuation of nevirapine, occurring a median of 5.3 weeks after starting the drug.

Contrary to other reports on the use of nevirapine in women, the percentage of serious adverse events in this study was higher in women with a low CD4 cell count. However, there were no significant differences in events, including rash and liver toxicity, between women with CD4 cell counts above and below 250 cells/ $\mu$ l. Researchers conclude that close monitoring for nevirapine toxicity is required, regardless of CD4 cell count.

Thomas T, *et al.* Twelfth Conference on Retroviruses and Opportunistic Infections, Boston, 2005 Abstract 809.

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## SINGLE SUTURE HOME BLOOD PRESSURE MONITORING

Home blood pressure monitoring is popular, but a report from Hong Kong indicates there is poor agreement between mercury sphygmomanometers and the automated devices used at home. The home devices have a sensitivity of 81% and a specificity of 80%. A fifth of devices had been bought on medical advice, but only 11% of participants in the trial knew that the cuff should be level with the heart, that they should rest for 5 minutes before taking their blood pressure, and that the size of the cuff is important.

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