Haematological changes in African children who received short-term prophylaxis with nevirapine and zidovudine at birth

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Summary We assessed the safety of short-term antiretroviral prophylaxis to prevent mother-to-child transmission (MTCT) of HIV by monitoring haematological changes in children up to the age of 18 months. Babies of HIV-infected women were randomised at birth to receive a single dose of nevirapine (NVP) alone or with zidovudine (ZDV) twice daily for a week. Based on the time of presentation to the labour ward, mothers of these babies might or might not have received intrapartum NVP. Complete blood counts were performed at birth and at 1.5, 3, 6, 9, 12, 15 and 18 months. Babies’ HIV status was determined by HIV-1 RNA testing. A total of 1755 babies were included in the study. Age-specific mean haemoglobin levels and prevalence of anaemia (haemoglobin $< 10$ g/dL) were not significantly different in cases where only the babies received a single dose of NVP and cases where NVP was given to mother/infant pairs or additional ZDV to the baby. Among HIV-infected children compared with uninfected children, the age-specific frequency of anaemia was significantly greater, anaemia started earlier and recovery to normal levels was slower and prolonged. A reversible granulocytopenia was observed in all children between 1.5 and 3 months of age. HIV infection significantly increased the children’s risk of death. Antiretroviral prophylaxis appeared to protect against anaemia and child death. Short regimens of antiretrovirals to prevent MTCT of HIV are not associated with long-term adverse haematological changes.

Introduction

Several studies have shown that short-term antiretroviral regimens of nevirapine (NVP) and zidovudine (ZDV) can reduce mother-to-child transmission (MTCT) of HIV among breastfed babies in Africa.1–6 Numerous antiretroviral trials are currently in progress in different parts of the world to determine if extending these regimens of NVP and/or ZDV reduces postnatal transmission associated with breastfeeding.

Use of NVP and ZDV in children is associated with haematological changes. For example, ZDV is associated with anaemia and neutropenia7 and NVP with anaemia, granulocytopenia and neutropenia. Haematological toxicities, however, are more common with prolonged use and higher doses. In most HIV perinatal trials using ZDV or NVP for up to 6 weeks, these