

## **Short postexposure prophylaxis in newborn babies to reduce mother-to-child transmission of HIV-1: NVAZ randomised clinical trial.**

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**BACKGROUND:** In sub-Saharan Africa, most women present late for delivery with unknown HIV status, which limits the use of intrapartum nevirapine to prevent mother-to-child transmission of HIV. We aimed to determine whether post-exposure prophylaxis of nevirapine plus zidovudine given to babies only reduced transmission of HIV more than did a regimen of nevirapine alone.

**METHODS:** We randomly assigned 1119 babies of Malawian women with HIV-1 who presented late (ie, within 2 h of expected delivery) to either nevirapine alone or nevirapine and zidovudine. Both drugs were given immediately after birth: one dose of nevirapine (2 mg/kg weight) was given as a single dose; babies in the nevirapine plus zidovudine group also received zidovudine twice daily for 1 week (4 mg/kg weight). Infant HIV infection was determined at birth and at 6-8 weeks. Primary outcome was HIV infection in babies at 6-8 weeks in those not infected at birth. Analysis was by intention to treat.

**FINDINGS:** The overall rate of mother-to-child transmission at 6-8 weeks was 15.3% in 484 babies who received nevirapine and zidovudine and 20.9% in 468 babies who received nevirapine only ( $p=0.03$ ). At 6-8 weeks, in babies who were HIV negative at birth, 34 (7.7%) babies who had nevirapine and zidovudine and 51 (12.1%) who received nevirapine only were infected ( $p=0.03$ )-a protective efficacy of 36%. This finding remained after controlling for maternal viral load and other factors at baseline. Adverse events were mild and of similar frequency in the two groups. **INTERPRETATION:** Postexposure prophylaxis can offer protection against HIV infection to babies of women who missed opportunities to be counselled and tested before or during pregnancy. The nevirapine and zidovudine regimen is safe and easy to implement.