



Postexposure prophylaxis to reduce MTCT of HIV infection

CITATION

Gray GE, et al. A randomized trial of two postexposure prophylaxis regimens to reduce mother to child HIV-1 transmission in infants of untreated mothers. *AIDS* 2005, 19:

RESEARCH QUESTION

Which prophylactic regimen administered to infants of HIV-positive mothers is more effective for reducing postuterine HIV infection: a single dose of NVP or ZDV for 6 weeks? Does breastfeeding influence the effectiveness of the two regimens?

THE STUDY DESIGN

Randomized, open-label trial

STUDY SETTING

3 public hospitals in South Africa. 1530 women enrolled between Oct 2000 and September 2002
Ethics approval obtained from RECs and mothers gave informed consent.

PARTICIPANTS

Infants included in study if mother HIV-positive when tested within 24 hours after infant's birth.
Excluded if preterm, weighed <1200g, required ventilation, unable to take oral medication, had congenital abnormalities.

INTERVENTIONS

- 1) Infant: NVP 10mg/ml oral suspension given as a single dose at 2mg/kg within 24 hr of delivery
- 2) Infant: ZDV 10mg/ml at a dose of 4mg/kg within 24 hrs of delivery then 12 hrly for 6/52

OUTCOMES

Primary

- Postuterine (intrapartum or early postpartum) infection at 12 weeks.*
- Serious adverse effects
- Infant mortality

* Postuterine infection = HIV negative at birth and positive on day 10 or more. Test for HIV infection = HIV-1 DNA positive by PCR.

Secondary

- Influence of breastfeeding on effectiveness

RISK OF BIAS (Risk Scale: Low – Moderate – High)

Selection bias: Low

Computer-generated random numbers. Allocation provided to nurses in sequentially numbered, non-transparent envelopes. Baseline characteristics similar. Modes of delivery not mentioned.

Performance bias: Moderate

Providers and mothers not blind

Attrition bias: High

Of 1051 infants 718 included in the analysis. Exclusion rate: 333/1051 (31.7%)

Detection bias: Moderate

Unclear if outcome assessors were blind

STUDY FINDINGS

	NVP	ZDV	
Outcomes			
Postuterine infection rates at 12 weeks but negative at birth" (Kaplan-Meier)	7.9%	13.1%	Logrank p=.06**
Serious adverse effects	94	118	P=0.56
Mortality <100 days	11	13	Logrank p= 0.8

**Logistic regression controlling for maternal HIV RNA, maternal CD4 count, breastmilk exposure gave an OR (95% CI) for ZDV use of 1.8 (1.1 to 3.2)

BOTTOM LINE

Postexposure prophylaxis using a single dose NVP is more effective than a 6 weeks course of ZDV for reducing the rate of postuterine HIV infection with no difference in the rates of serious adverse effects or death in infants.

Prepared by: Jimmy Volmink

5 June 2006