

Abstract Preview - Step 3/4

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Topic: C2 Antiretroviral interventions for pregnant women to prevent transmission

Title: Triple-antiretroviral (ARV) Prophylaxis during Pregnancy and Breastfeeding Compared to Short-ARV Prophylaxis to Prevent Mother-to-Child Transmission of HIV-1 (MTCT): The Kesho Bora Randomized Controlled Clinical Trial in Five Sites in Burkina Faso, Kenya and South Africa (Trial registration number ISRCTN71468401).

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Text: **Background:** ARV interventions to reduce MTCT during late pregnancy and delivery are well established, but no randomized trial has assessed safety and efficacy of continued maternal ARVs during breastfeeding.

Methods: Between June 2005 and August 2008, HIV-infected pregnant women with CD4 200-500 cells/mL were randomized between 28 and 36 weeks of pregnancy to triple-ARV (ZDV+3TC+LPV/r to 6.5 months post-delivery or breastfeeding cessation if earlier) or short-ARV (ZDV through delivery plus single-dose NVP in labour). Infants received single-dose NVP. From September 2007, 1 week maternal ZDV+3TC was added to short-ARV regimen postpartum and 1 week ZDV for all infants. 12-month cumulative lifetable rates were compared using logrank tests.

Results: 824 women (413 triple-ARV, 411 short-ARV) delivered 805 live, singleton or first-born infants. Median enrolment CD4 was 335; 56% had CD4 200-350. By May 2009 all infants had been born ≥ 6 and 87% ≥ 12 months previously. 77% were breastfed median duration 21 weeks in both arms. 12-month cumulative incidence of HIV infection or death was 10.4% (95% CI 7.7-14.9%) [40 endpoints] with triple-ARV and 16.3% (13.0-20.5%) [62 endpoints] with short-ARV (36% risk reduction, $p=0.023$). 56 infants were infected by 12 months, 37 born to mothers with CD4 200-350; another 46 died. Cumulative HIV infection rates (95% CI) [infections] were:

Age	Birth	6 weeks	6 months	12 months
Triple-ARV	1.8% (0.8-3.7) [7]	3.3% (1.9-5.6) [13]	4.9% (3.1-7.5) [19]	5.6% (3.4-8.4) [21]
Short-ARV	2.0% (1.0-4.0) [8]	4.5% (2.9-7.1) [18]	8.2% (5.9-11.5) [32]	9.3% (6.7-12.7) [35]

[Table]

Reduction in HIV infections by 12 months was 40% ($p=0.052$). There was no increase in adverse events with triple-ARV.

Conclusions: Twelve-month HIV-free survival was significantly better when mothers with CD4 200-500 received triple-ARV prophylaxis. Largest effect (HIV infections averted) was observed between 6 weeks and 6 months postpartum when ARV prophylaxis was received in triple-ARV but not short-ARV arm; and among women with CD4 200-350.

Country of research: Burkina Faso, Kenya, South Africa

Ethical Research Declaration: Yes

The research presented in this abstract specifically relates to the needs of women and girls

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