

Abstract

To evaluate strategies to reduce HIV-1 transmission through breastfeeding, a multicentre study including a nested randomized controlled trial was implemented in five research sites in West, East and South Africa (The Kesho Bora Study). The aim was to optimize the use of antiretroviral (ARV) drugs during pregnancy, delivery and breastfeeding to prevent mother-to-child transmission of HIV-1 (PMTCT) and to preserve the health of the HIV-1-infected mother. The study included long-term ARV treatment for women with advanced disease, and short-course ARV prophylaxis stopped at delivery for women with early disease. Women with intermediate disease participated in a randomized controlled trial to compare safety and efficacy of triple-ARV prophylaxis prolonged during breastfeeding with short-course ARV prophylaxis stopped at delivery. Between January 2005 and August 2008 a total of 1140 women were enrolled. This paper describes the study design, interventions and protocol amendments introduced to adapt to evolving scientific knowledge, international guidelines and availability of ARV treatment. The paper highlights the successes and challenges during the conduct of the trial. The Kesho Bora Study included one of the few randomized controlled trials to assess safety and efficacy of ARV prophylaxis continued during breastfeeding and the only randomized trial to assess maternal prophylaxis started during pregnancy. The findings have been important for informing international and national guidelines on MTCT prevention in developing countries where, due to poverty, lack of reliable and affordable supply of replacement feed and stigma associated with HIV/AIDS, HIV-infected women have little or no option other than to breastfeed their infants. (ISRCTN71468401).