



DFID MSP PROJECTS: KESHO BORA STUDY

Project Title: The impact of highly active antiretroviral treatment during pregnancy and breastfeeding on MTC and mothers' health

Service Provider: University of KwaZulu Natal

Partner: KwaZulu Natal DoH

Aim

The Kesho Bora project is part of an ongoing multi-country study coordinated by the World Health Organisation (WHO). It aims to determine the optimal use of antiretroviral drugs during pregnancy, delivery and breastfeeding in order to reduce HIV transmission while minimizing the risk of drug toxicity and drug resistance. The study is a randomized controlled trial that observes a cohort of mothers and children for two years after delivery.

Location

The study has 5 implementing sites across Africa, including Kwadebeka Clinic on the outskirts of Durban in KwaZulu Natal, where HIV prevalence among pregnant women is over 40%.

Project description

The study aims to test the hypothesis that triple drug antiretroviral therapy (HAART) during the period of pregnancy and breastfeeding is more effective than short course standard PMTCT in mothers with intermediate immune suppression (CD4 counts between 200 and 500). The study compares a trial group (on triple regimen ZDV, 3TC and Kaletra) with one on a short-course ARV regimen (ZDV twice daily during the last month of pregnancy, plus single dose NVP at onset of labour).

Primary objectives are to compare the two groups with regard to:

- HIV-free infant survival at 6 weeks and 12 months;
- AIDS-free survival of mothers 12 months after birth and
- Incidence of severe adverse effects in mothers, including resistance.

Recruitment began at the Durban site in February 2007 and was completed in August 2008 with 191 participant enrolled. It will provide the first set of interim results in July 2009 and these will be presented to the National Department of Health. They will also be presented to the International AIDS Society conference at the same time. The results of this important trial will inform national and international policy and recommendations.

Outcomes

The results of the trial have not yet been published. However there have been some positive preliminary outcomes:

- Of the 168 infants in the trial group tested at 6 weeks, only 6 were found to be PCR positive (3.5%).
- 13 mothers with CD4 counts less than 200 were referred for HAART.
- There were only ten missed clinic visits recorded up to June 2008.
- The Kwadabeka Clinic site showed the lowest error of all study sites. This reflected the commitment of the clinic staff to the project and the support of clinic management.