

# MICROBICIDES DEVELOPMENT PROGRAMME

## Medical Research Council

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## International HIV Clinical Trials Research Management Office

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## MDP 301 Quick Facts

### Study Overview

- MDP 301 was a Phase III trial evaluating the safety and effectiveness of the vaginal microbicide PRO 2000 for reducing the risk of HIV infection in women.
- The trial took place between September 2005 and September 2009 and enrolled 9385 women at 6 research centres in South Africa, Tanzania, Uganda and Zambia.
- Participants were originally randomised in approximately equal numbers to one of three study groups: PRO 2000 gel 0.5% dose, PRO 2000 gel 2% dose and placebo (gel with inactive ingredient). In February 2008, an independent monitoring committee recommended that no more women should be allocated to 2% PRO 2000 gel as there was little chance that it would prove effective. The trial promptly stopped dispensing the 2% gel to all women who had been allocated to it but these women continued to be followed up. All women enrolling subsequently were randomised to the other two study groups.
- Participants were instructed to apply gel up to one hour before sexual intercourse. They were counselled on safe sexual behaviour and encouraged to use condoms, which were provided free of charge.
- The trial was run by the Microbicides Development Programme, a not-for-profit partnership funded by the UK government through its Department for International Development and the UK Medical Research Council. For more information on the Programme, see: <http://www.mdp.mrc.ac.uk>

### Achievements and 'Firsts'

- MDP 301 was the largest trial of a vaginal microbicide ever undertaken and the only one funded by a European government.
- Historically, new drugs have not been affordable in developing countries where impacts of disease can be most severe. MDP's contract with the product developer contained provisions to help ensure affordable access for women in developing countries, had the product been proved to be effective.
- Social science research was integrated into MDP 301 to help ensure that women would find microbicides acceptable, affordable and easy to use if eventually marketed. Behavioural findings were also used to help manage the trial and understand its results.
- The trial recruited volunteers directly from communities rather than exclusively from medical facilities, and this was made possible by innovative community liaison structures.

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- MDP 301 helped to establish a new laboratory in Zambia and provided a range of support enabling a major laboratory in Uganda to receive official accreditation. A further four African laboratories are applying for accreditation. The trial achieved permanent improvements in Good Clinical Laboratory Practice across sites and helped create the foundation for a future pan-African laboratory network.
- Unlike many other international trials, MDP 301 was structured to ensure that African trial centres owned and controlled their own data. Local data management occurred on site and African investigators had direct access to their own site data for scientific papers.
- MDP support will have enabled at least 12 African staff to complete higher education and another 12 or more to achieve advanced degrees. At a recent international conference, roughly 50 African co-authors from MDP centres presented, between them, roughly 36 papers or posters. At least a dozen were giving academic presentations for the first time in their careers.
- Costs of the trial were less than a third of what they would have been in comparable industry-sponsored trials, according to a recent benchmarking report (<http://bit.ly/5p63kS>). Infrastructure for MDP 301 was relatively modest and UK partners received academic-scale salaries which were underwritten by their host universities.

## Reasons for the study

- The development of a prevention method for women could save millions of lives. Globally, in 2007, there were nearly 3 million new HIV infections and 2 million HIV-related deaths.
- Over 33 million people are infected with HIV and women are especially susceptible. Worldwide, HIV/AIDS is the leading cause of death for black women aged 25–34.
- Women account for nearly 60% of HIV infections in sub-Saharan Africa, where MDP concentrates its research. Many are highly vulnerable to HIV despite the fact that they are married and faithful to their partners. This region also has the world's largest population of children living with HIV.
- Heterosexual intercourse remains the epidemic's driving force in sub-Saharan Africa. Currently, women do not have a method of protection that they can use on their own. A microbicide would put women's safety much more in their own hands.