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HIV 'prevention' gel PRO 2000 proven ineffective

14 December 2009

The largest international clinical trial to date into a preventative HIV gel has found no evidence that the vaginal microbicide PRO 2000 reduces the risk of HIV infection in women, scientists announced today.

This placebo-controlled trial involved 9,385 women at six research centres in four African countries and found that the risk of HIV infection in women who were supplied with PRO 2000 gel was not significantly different than in women supplied with placebo gel. Although ineffective in providing protection, PRO 2000 gel itself was safe to use.

A vaginal microbicide is a product intended for use before sexual intercourse to help reduce HIV infection, as it is clear that condom promotion alone has not controlled the epidemic. The gel was given to participants together with a package of prevention against HIV infection that included free condoms, counselling for safer sex negotiation and sexual health throughout the trial.

The trial, known as MDP 301, took place between September 2005 and September 2009 and was carried out by the Microbicides Development Programme (MDP), a not-for-profit partnership of 16 African and European research institutions. It was funded by the UK Department for International Development (DFID) and the UK Medical Research Council (MRC).

To date, no microbicide has been shown to be effective against HIV infection. This trial shows conclusively that PRO 2000 gel is of no added benefit, ending scientific speculation about its clinical importance.

MDP 301 Chief Investigator, Dr Sheena McCormack of the Medical Research Council said: "This result is disheartening; particularly in light of the results of a smaller trial sponsored by the US National Institutes of Health (NIH) which suggested that PRO 2000 could reduce the risk of HIV infection by 30 per cent. Nevertheless we know this is an important result and it shows clearly the need to undertake trials which are large enough to provide definitive evidence for whether or not a product works."

Professor Jonathan Weber, co-Chair of the MDP Programme Management Board from the Division of Medicine at Imperial College London, said: "This is a disappointing result for the product, as the trial shows that it is not effective. However, the trial itself was very well designed and undertaken, so we know that the results are definitive. It is unfortunate that this microbicide is ineffective at preventing HIV infection, but it's still vital for us as scientists to continue to look for new ways of preventing HIV. There are many research groups exploring different avenues to tackle HIV; it is a slow process, but we are making progress. Now that we know this microbicide is not the answer, we can concentrate on other treatments that might be."

Dr Maureen Chisembele, Principal Investigator of the Zambian site, said: "In Sub-Saharan Africa, nearly 60 per cent of all people living with HIV/AIDS are women. Many are highly vulnerable to HIV despite the fact that they are faithful to their partners. The women will be disappointed by this result as they really liked the gel and hoped it would work."

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A South African trial participant commented: "Even though the gel proved not to be effective, we played a role in the fight against HIV. We learnt a lot about caring for ourselves, such as using condoms. We also learnt to encourage others to test for HIV and we gained confidence in helping those who were already infected."

The trial participants are being informed of the trial outcome. The full results will be submitted for presentation at international conferences in 2010, as well as for publication in a peer-reviewed scientific journal.

The gel used in the study was provided by Endo Pharmaceuticals, a specialty pharmaceutical company with headquarters in Chadds Ford, Pennsylvania, USA.

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Notes for editors:

1. For media queries, please contact the MRC press office on 0207 637 6011 or press.office@headoffice.mrc.ac.uk

2. More information about the MDP 301 microbicides trial can be found at http://www.mdp.mrc.ac.uk/

3. There were 130 HIV infections out of 3,156 women who were given 0.5% PRO 2000 gel, and 123 HIV infections out of 3,112 given the placebo gel in the main analysis. The rates of HIV infection were very similar in both groups: 4.5 per hundred women years in the 0.5% PRO 2000 group, and 4.3 in the placebo group. Thus 0.5% PRO 2000 gel did not reduce the risk of HIV infection, and this was confirmed in the statistical analysis. The measure 'per hundred women years' takes into account the varying periods of time the women participated in the trial as well as the number of women involved and is used to calculate the risk of becoming infected by HIV. This is also known as the incidence rate.

4. Trial participants were randomly assigned to PRO 2000 gel or a placebo gel group. Women were asked to use the gel before each sex act and were also given condoms and counselled to use them together with gel. Women were followed up for 12 months (or up to 24 months in Uganda) and were evaluated regularly. All were provided with safe sex counselling, treatment for sexually transmitted infections and referral for other non trial-related medical conditions

5. The trial also included a major social science component which has yielded important new information about sexual behaviour and adherence, as well as factors which encourage or inhibit condom use. The social science research was coordinated by the London School of Hygiene and Tropical Medicine and the Barcelona Centre for International Health Research.

6. MDP 301 was conducted at the following research centres (principal investigators at each centre are named in parentheses): University Teaching Hospital, Lusaka, Zambia (Dr Maureen Chisembele); Medical Research Council Uganda Virus Research Institute, Entebbe (Dr Anatoli Kamali); African Medical and Research Foundation and National Institute for Medical Research, Mwanza, Tanzania (Prof Richard Hayes); the Africa Centre for Health and Population Studies, KwaZulu-Natal, South Africa (Mitzy Gafos); South African Medical Research Council, Durban, South Africa (Prof Gita Ramjee); and the Reproductive Health and HIV Research Unit, Department of Obstetrics and Gynaecology, University of Witwatersrand, Johannesburg, South Africa (Prof Helen Rees). Contract Laboratory Services of South Africa (Prof Wendy Stevens) served as a central reference laboratory for serology testing and confirmation and provided Good Clinical Laboratory Practice training to nearly 60 laboratory staff at the research centres. Feasibility studies for future trials have been carried out in Mozambique, at the Health Research Centre in Manhiça and at Mavalane Hospital in Maputo (Dr Sibone Mocumbi).

7. A trial of this scale and complexity could not have been completed without the involvement of many people across Africa, Europe and the US. MDP thanks all the participants, staff and communities whose enthusiasm and commitment made this study possible. They also extend their thanks to their colleagues in the field of microbicides and HIV prevention whose work contributed to this study.

8. Coordination of the trial was provided by the Clinical Trials Unit of the UK Medical Research Council and Imperial College London.

Other European partners involved in MDP 301 included the London School of Hygiene and Tropical Medicine; St. George's Hospital, London; and the Universities of York, Southampton and Barcelona.

9. The MDP 301 trial leaves a strong legacy. New laboratories have been equipped and accredited. Research centre staff have gained experience and training in conducting clinical trials to the highest international standards. Many were supported to acquire degrees and diplomas which will advance their careers. Thousands of women have received counselling that will help them practise safer sex and lead healthier lives. The trial has helped many women to discuss HIV prevention with their partners.

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