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Final results of largest ever HIV microbicide trial revealed

20 September 2010

Results from the largest international clinical trial to date into a preventative HIV gel are published today in the Lancet. The trial found that, although safe, there was no evidence that the vaginal microbicide PRO 2000 reduces the risk of HIV infection in women. The trial was part-funded and sponsored by the Medical Research Council (MRC).

A crucial finding from the study published today shows that women enrolled on the trial were willing to use the gel as part of their regular sexual routine, with 89 per cent of women reporting that they had used the gel the last time they had sex. By showing that the women and their partners found the gel acceptable, this trial paves the way for a future effective microbicide, which would offer women the first ever autonomous method of HIV protection.

The placebo-controlled trial MDP 301 involved over 9,000 women at six research centres in four African countries. It found that the risk of HIV infection in women who were supplied with PRO 2000 gel was much the same in women supplied with placebo gel. For the benefit for the women who took part in the trial, the headline results outlining the safety and ineffectiveness of the gel were announced in December 2009.

Dr Sheena McCormack from the MRC Clinical Trials Unit and MDP 301 chief investigator says:

"Of course we are disappointed that the gel was shown not to be effective, especially after the promising signal seen in a preceding trial conducted by the NIH funded HIV Prevention Trials Network. However MDP301 is still an important scientific result and it shows clearly the need to undertake independent trials to provide robust evidence for whether or not a product works. It would not have been possible to carry out such a complex trial without the crucial partnerships between African and European researchers, and above all the participation and commitment of the women in the trial."

Results from a subsequent microbicide trial, CAPRISA 004, were published in July of this year showing that, when used before and after sex, an anti-retroviral gel called tenofovir reduces the risk of HIV infection by 39 per cent and herpes infection by 51 per cent. The trial was led by the Center for the AIDS Program of Research in South Africa (CAPRISA) at the University of KwaZulu-Natal and involved nearly 900 women. This groundbreaking trial provides proof that a microbicide can reduce the risk of HIV infection in women.

Dr McCormack continues:

"'The desperation of the HIV epidemic and the urgent need to find a method of protection that can be administered by both men and women hasn't gone away. Researchers now need to build on the positive CAPRISA 004 results for tenofovir by conducting independent trials in broader populations ideally looking at simpler regimens to pave the way for programmatic roll-out."

The MDP 301 trial took place between September 2005 and September

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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 Medical Research Council (MRC).

The partnership involved both African and European researchers and enhanced the collective capacity to deliver large scale complex trials in resource-poor settings, working in collaboration with community authorities and members.

PRO2000 vaginal gel for prevention of HIV-1 infection (Microbicides Development Programme 301) a phase 3, randomised, double-blind, parallel-group trial is published in the Lancet today, 20 September 2010.

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

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

3. 3. A vaginal microbicide is a product intended for use as part of a sexual routine 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.

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

5. 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.

6. 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.

7. 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).

8. 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.

9. 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.

The Medical Research Council

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