

## Summary of trials of PRO 2000: HPTN 035 and MDP 301

	HPTN 035	MDP 301
Primary endpoint	Evaluate safety and efficacy of 0.5% PRO 2000/5 and Buffergel in reducing acquisition of HIV in HIV-negative women	Measure safety and effectiveness of 0.5% PRO 2000 gel and 2% PRO 2000 gel in reducing risk of HIV acquisition when compared to placebo gel
Sponsor	HIV Prevention Trials Network, funded by the US National Institutes of Health	UK Medical Research Council, funded by UK Department for International Development
Study teams and sites	<ul style="list-style-type: none"> <li>• Malawi College of Medicine – Johns Hopkins University Clinical Research Site, Blantyre, <b>Malawi</b></li> <li>• University of North Carolina Lilongwe Clinical Research Site, Lilongwe, <b>Malawi</b></li> <li>• Chatsworth Clinical Research Site, South African Medical Research Council (MRC), Durban, <b>South Africa</b></li> <li>• Hlabisa Clinical Research Site of the MRC, KwaZulu-Natal, <b>South Africa</b></li> <li>• Centre for Infectious Disease Research in Zambia, Lusaka, <b>Zambia</b></li> <li>• University of Zimbabwe-UCSF Collaborative Research Programme, Harare, <b>Zimbabwe</b></li> <li>• University of Pennsylvania, <b>USA</b></li> </ul>	<ul style="list-style-type: none"> <li>• University Teaching Hospital, Lusaka, <b>Zambia</b></li> <li>• MRC Uganda Virus Research Institute, Entebbe, <b>Uganda</b></li> <li>• African Medical and Research Foundation and National Institute for Medical Research, Mwanza, <b>Tanzania</b></li> <li>• African Centre for Health and Population Studies, KwaZulu Natal, <b>South Africa</b></li> <li>• South African Medical Research Council, Durban, <b>South Africa</b></li> <li>• Reproductive Health and HIV Research Unit, Johannesburg, <b>South Africa</b></li> </ul>
Participants	3,099 HIV-negative women	9,404 HIV-negative women
Study arms	<ul style="list-style-type: none"> <li>• PRO 2000 0.5% gel + prevention package</li> <li>• Buffergel + prevention package</li> <li>• Placebo + prevention package</li> <li>• Prevention package (no gel)</li> </ul>	<ul style="list-style-type: none"> <li>• PRO 2000 0.5% gel + prevention package</li> <li>• PRO 2000 2% gel + prevention package</li> <li>• Placebo + prevention package</li> </ul>
About the trials	<ul style="list-style-type: none"> <li>• Both trials were double-blind, meaning none of the participants, clinic staff or investigators knew which participants were assigned to which arm of the study (except in the case of the no-gel arm in the HPTN study). Participants were counseled repeatedly that there was no evidence that PRO 2000 would prevent HIV infection, and that they did not know whether they were using a placebo or the PRO 2000. Therefore, they should continue to use proven HIV prevention strategies to reduce their risk of contracting HIV.</li> <li>• Ethical review boards in trial countries as well as the UK (for MDP) and the US (for HPTN) approved the trial design, indicating that the review boards found the trial designs to be protective of the rights and welfare of the research participants. All participants in both trials received a standard prevention package, including treatment for sexually transmitted infections, condoms and behavior change counseling. In some sites, trial staff also referred participants for services for social issues like domestic violence, conducted support groups, and offered other interventions according to needs that emerged among trial participants.</li> <li>• The MDP trial initially included an additional active arm testing 2% PRO 2000 gel. This arm was discontinued for “futility” following a February 2008 meeting of the trial’s Independent Data Monitoring Committee (IDMC). After reviewing the data, the IDMC concluded that the 2% gel was not likely to show any benefit in reducing acquisition of HIV. The final results of the MDP 301 trial will include information on HIV infections and side effects for the women who were in the 2% gel arm of the study. This will be an important to assessing the overall safety and effectiveness of PRO 2000.</li> </ul>	