



MEDIA CENTER  
*Microbicides News*

NEW YORK, NY (31 January 2007) — CONRAD and FHI announced their decision to halt Phase III clinical trials of cellulose sulfate, a candidate microbicide, because preliminary results indicated that cellulose sulfate could lead to an increased risk of HIV infection in women who use the compound. Microbicides are products being developed to reduce the transmission of HIV—and possibly other sexually transmitted infections—when used during intercourse. Cellulose sulfate was one of four first-generation microbicide candidates in effectiveness trials for the prevention of HIV and other sexually transmitted infections. The cellulose sulfate trials were stopped after a review by the trial’s Independent Data Monitoring Committee. Independent monitoring groups play a critical oversight role in clinical trials, helping to ensure participants’ safety.

The Population Council is nearing completion of a Phase 3 clinical trial with more than 6,000 women to test the efficacy and long-term safety of a different candidate microbicide—Carraguard®. Carraguard is a noncontraceptive product made from carrageenan, which is derived from seaweed. Carrageenan has been used for hundreds of years in food and cosmetics.

An external, independent data safety monitoring board reviewed the Carraguard safety data at three points during the trial and found no indications of a safety risk to trial participants.

The Phase 3 trial is taking place in three sites in South Africa. Enrollment concluded in June 2006, and the trial will be completed by the end of March 2007, with results expected at the end of 2007.

All of the women participating in the trial received intensive HIV prevention counseling, including free condoms. The safety of the women participating in the trial has been carefully monitored throughout the trial by quarterly visits that have included HIV testing, gynecologic examinations and treatment of sexually transmitted diseases, and careful recording of all adverse events.

Prior to starting the Phase 3 trial, five previous studies involving more than 500 women and men from seven continents demonstrated that Carraguard is safe for vaginal use and was acceptable to HIV-negative and HIV-positive women and men when used for up to 12 months.

The Population Council is committed to improving protection strategies for girls and women globally, including microbicide research, which has featured prominently in the Council’s work for nearly 20 years. It is important that we continue working vigorously in the laboratory and in the world’s most affected areas to advance the search for a safe and effective microbicide.

For more information: CONRAD news release:

<http://www.conrad.org/press/phaseIIItrials.htm> FHI news release:

[http://www.fhi.org/en/AboutFHI/Media/Releases/res\\_CS\\_Nigeria.htm](http://www.fhi.org/en/AboutFHI/Media/Releases/res_CS_Nigeria.htm)