

Einstein to develop anti-HIV drug delivery system

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The National Institutes of Health has awarded Albert Einstein College of Medicine of Yeshiva University a four-year, \$7.2 million grant to develop a microbicide-releasing vaginal ring to prevent HIV transmission.

"While condoms are excellent at preventing the transmission of [HIV](#), it's often difficult for women to negotiate their use," says principal investigator Betsy C. Herold, M.D., professor of pediatrics, of microbiology & immunology, and of obstetrics & gynecology and women's health at Einstein. "It's imperative that women have alternative strategies available to protect their own health. Our belief is that an intravaginal ring that delivers a combination of drugs is the best strategy."

Vaginal rings are soft, plastic, doughnut-shaped devices designed to provide controlled release of drugs to the vagina over extended periods. At present, there are several models available for delivering contraceptives, but none for microbicides.

Dr. Herold and her colleagues will evaluate several anti-HIV microbicides, ultimately aiming for a two-drug combination. "Over the last decade, we've learned that when you expose HIV to a single drug, you make it easier to select for resistance," she says. "So, we are trying to target HIV infection at two different steps very early in its life cycle, which should prevent the establishment of any infection."

One of the drugs to be evaluated is tenofovir, which blocks reverse transcriptase, an enzyme crucial to HIV reproduction. Tenofovir is used currently as an oral systemic therapy against HIV, but it has also shown promise as a topical microbicide. The team will also test the efficacy of two so-called fusion inhibitors, including maraviroc and PIE12-trimer, which block the virus from entering target immune cells by different mechanisms.

The team will pay particular attention to choosing microbicides that preserve natural vaginal defenses against HIV. In recent years, supposedly safe microbicides were found to make women more susceptible to HIV infection. As Dr. Herold demonstrated in an earlier study, (<http://www.einstein.yu.edu/home/news.asp?id=381>) these microbicides most likely failed because they disrupted the vagina's epithelial lining, which provides a protective barrier against infection.

"We want to preserve that protective barrier while adding drugs that will be at the right place at the right time when the virus presents," says Dr. Herold. "That is why a ring, which can provide sustained delivery of the [microbicide](#) over three to four weeks, would be ideal. People wouldn't have to remember to use it, which is a problem with gels and pills. Also, we don't know if oral medications will get to the right place - some drugs get into the genital tract well, but some don't." The ring could be replaced monthly without a doctor's supervision.

The microbicides will be incorporated into vaginal ring under development at the University of Utah, Department of Bioengineering, which is collaborating on the study.

"We've deliberately chosen to focus on drugs that have already been approved for systemic use or are far along in the regulatory process. This should shorten the time it takes to begin clinical trials. We know that every day that goes by, more people are getting infected with HIV," says

Dr. Herold. The researchers hope to start Phase I clinical testing within the next four years.

The need for a microbicide-releasing vaginal ring is especially urgent in sub-Saharan Africa, where the infection rate among 15 to 49 year-olds exceeds 23 percent in some countries. AIDS is the leading cause of death in sub-Saharan Africa and women account for six out of ten of those living with HIV. "But this is not just a global health problem," says Dr. Herold. "This is a problem here in the U.S. The rates of HIV in certain regions in this country parallel the rates in many areas of developing world."

According to the Centers for Disease Control and Prevention, the national infection rate in the United States is 1 percent; in D.C., it is 3 percent, and in the Bronx, 1.7 percent. While men still have higher rates of infection than women in the U.S., AIDS is a common killer for women - ranking third after cancer and heart disease. As of 2007, there were 9,000 women with HIV/AIDS living in the Bronx.

Source: Albert Einstein College of Medicine ([news](#) : [web](#))

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