

HIV trial scrapped after gel found to be ineffective

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In a major setback for AIDS prevention research, a clinical trial of a new vaginal gel supposed to reduce HIV infections has been suspended after studies showed it to be ineffective.

Researchers from the Microbicide Trials Network, set up by the US National Institutes of Health (NIH), expressed surprise at the outcome as a previous study on a gel containing the drug [tenofovir](#) had shown encouraging results.

Researchers are striving to produce a gel or a pill that protects women against [HIV infection](#) but still allows them to get pregnant so it can be used in sub-Saharan Africa and other places where [condom use](#) can be a problem.

A first trial by the Centre for the AIDS Programme of Research in South Africa (CAPRISA) showed reduced HIV infections in 39 percent of women treated with the tenofivir gel, and in 54 percent of those who used it regularly.

Those results, published in 2010, raised hopes that a new gel could slow the [transmission of HIV](#)/AIDS and finally provide women with a groundbreaking means of protecting themselves.

Observers had hoped VOICE (Vaginal and Oral Interventions to Control the Epidemic), a trial started in September 2009 and conducted with the help of 5,000 women in South Africa, Uganda and Zimbabwe, would

back those findings.

An interim review of VOICE by an independent data and safety monitoring board, however, determined that the tenofovir gel was even less effective than a placebo. Part of the research has now been canceled.

Another area of the three-part trial, involving a tenofovir pill, was scrapped in September for similar reasons, but studies are ongoing on a third avenue using tenofovir and a booster drug.

"For now, the study will continue and we will work to complete the remaining visits for the women continuing in the study," researchers Sharon Hillier and Ian McGowan wrote.

"We are all eager to understand whether adherence, our daily dosing strategy, inflammation or other factors could explain the lack of oral and vaginal tenofovir effectiveness in VOICE, we will not likely have all of the assays completed until later next year."

Hillier said she was "surprised and disappointed" by the results, and the researchers said they must wait until the end of the remaining trial before a fuller analysis could be undertaken.

CAPRISA director Salim Abdool Karim, a site director in the VOICE trial, admitted to being gravely disappointed.

"These results were totally unexpected as there is good evidence from laboratory research, animal studies and human trials showing that tenofovir [gel](#) prevents HIV. However, science does not always produce the answer we hope for," he said.

"This is particularly pertinent when a drug's effectiveness is dependent

on a complex combination of the biological activity of the drug and the human behavior influencing use of the drug as prescribed during the study.

"I look forward to seeing the complete results and, in particular, an analysis of whether the drug levels in the female genital tract provides any clues to the study's outcome."

Despite the setback, there have been other encouraging signs in the HIV/AIDS struggle in recent years.

In South Africa, whose population of 5.6 million HIV-infected people is the biggest in the world, the incidence rate fell by a third between 2001 and 2009, from 2.4 percent to 1.5 percent.

But the sub-Saharan African region continues to have the largest number of people infected with HIV.

In 2010, they made up some 68 percent or 22.9 million of all HIV-infected people.

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