

Prototype vaginal gel fails to block HIV: study

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A vaginal gel failed to protect women against the AIDS virus, doctors said on Monday, reporting on a major clinical trial that enrolled more than 9,000 women.

The formula, known as PRO 2000, was tested in a Phase III trial, the widest and most exhaustive stage of the process to assess a new drug for safety and effectiveness.

AIDS campaigners have staked huge faith in the search for a vaginally-used gel to thwart the [human immunodeficiency virus](#) (HIV). It would revolutionise the fight on AIDS by empowering women, especially in African countries where coercive sex is a problem.

The first breakthrough in this quest was announced in July at the 18th International AIDS Conference in Vienna.

Scientists reported that a cream tested in a Phase IIb trial in South Africa called CAPRISA 004 cut the risk of [HIV infection](#) by 39 percent overall, and by 54 percent among those women who used it most consistently.

This level of protection may not be enough to make the CAPRISA gel get approval, however.

The cream incorporates tenofovir, a drug commonly used in tablet form to quell HIV by disrupting its reproduction in [immune cells](#).

The PRO 2000 formula is different, being a so-called large charged polymer, which is intended to disrupt HIV's interaction with targeted cells.

It was tested at two levels of concentration, of two percent and 0.5 percent, in 13 clinics in South Africa, Tanzania, Uganda and Zambia in a trial that was closely monitored for ethical standards.

Volunteers were women who were aged 18 years or older, were sexually active and did not have HIV. They were given either the gel or an inactive dummy cream called a placebo. All were given counselling on [safe sex](#) and access to condoms.

Their HIV status was then tested at 12 weeks, 24 weeks, 40 weeks and 52 weeks after starting with the product.

PRO 2000 was found to be safe but ineffective, according to the report card, published online by The Lancet.

"Safety-related events were rare and at similar rates in all three groups... (but) HIV-1 incidence was much the same between groups at study end," it said.

In an important detail, use of the gel -- a big challenge in microbicides -- was high. Eighty-nine percent of the women said they used it prior to intercourse.

Twenty-five million people have been killed by AIDS and more than 33 million others today are infected by [HIV](#), which causes the disease.

More than two-thirds of these live in sub-Saharan Africa, where 60 percent of the estimated 1.9 million new infections in 2008 occurred among women and girls.

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