

Rectal pill may give days-long protection against HIV: Study

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Could a quick-dissolving pill placed in the rectum prove to be an

effective and safe "on-demand" way to prevent HIV infection among sexually active men and women?

It might, new research indicates.

The experimental form of PrEP (pre-exposure prophylaxis) is designed to be placed directly into either the rectum or the vagina. In the new study, conducted among 21 men and women, it delivered high levels of protective [antiretroviral drugs](#) for up to three days following a single insertion in the rectum, with negligible side effects. Previous research has already tested inserting the [pill](#) into the vagina.

Still, the finding is preliminary. And importantly, investigators have not yet run tests to see if the delivery method actually prevents HIV [infection](#) in people. While research has focused on whether the pill effectively exposes a patient's rectal or vaginal area to the medication at hand, [laboratory tests](#) have also sought to simulate and assess HIV prevention effectiveness.

The ultimate goal, say investigators, is to add yet another PrEP [delivery method](#) to the growing menu of oral and injectable options that at-risk men and women can use.

"This is the first insert [rectal pill] to be developed for HIV prevention," explained study author [Dr. Sharon Riddler](#), associate chief of clinical research in the University of Pittsburgh's Department of Medicine.

Composed of two antiretroviral drugs—20 milligrams (mg) of tenofovir alafenamide (TAF) and 16 mg of elvitegravir (EVG)—the suppository is "meant to be used as needed prior to sexual activity, placed in the rectum or vagina, where it will dissolve," Riddler explained.

First approved by the U.S Food and Drug Administration back in 2012,

a daily oral dose of the antiviral drug cocktail known as PrEP is considered to be a nearly foolproof way to prevent HIV infection following sexual exposure.

According to the U.S. Centers for Disease Control and Prevention, when oral antiviral PrEP pills are taken as instructed, they lower the risk for HIV infection by roughly 99%.

And the CDC notes that the two pills on the market—sold under the brand names of Truvada and Descovy—are also at least 74% effective at preventing HIV infection among injection drug users.

Those at high risk for HIV can also choose to take PrEP off-label using on an "on demand" regimen, ingesting the pill just before and just after resuming sexual activity, rather than on daily basis. Though this intermittent method is not officially approved by the FDA, it is also believed to offer near complete protection against HIV infection.

In late 2021, yet another effective option became available, in the form of a once-every-two-months injection version of PrEP called Apretude.

In the latest study, work with the new insert involved 15 men and 6 women, all of whom were HIV-negative.

For the first round of testing, all were given the rectal pill to take in a clinical setting. Blood and rectal tissue samples were then obtained several times over the course of the three following days.

A second round of testing was then conducted within the following seven weeks, at which point all were given two of the rectal pills to use together. Samples were again collected in a similar fashion.

The result: After both the first and second round of testing, high levels

of the antivirals were found in both rectal tissue and fluid.

Laboratory tests—not yet replicated in people—further indicated that both the one and two-dose regimen appeared to prevent HIV infection for up to three days, though the two-dose regimen was found to provide greater protection.

And, "in the current study, the inserts were very safe and well-tolerated," Riddler noted. "No significant side effects, though it is a small study."

"The next step will likely be a longer study, where participants use the insert for multiple times over a period of months to gather more information" on safety, side effects, drug levels and the degree to which people actually want to use this latest version of PrEP, she said.

The latter is likely a critical question, given that those at high-risk for HIV infection already have highly effective treatment options.

As to why patients might use an inserted pill, Riddler noted that—for one thing—the method under investigation is "the only topical product that is in development that may be able to be used in the vagina *or* the rectum. So this might be an attractive option for people who have both vaginal and anal sex practices who do not want to take pills or injections."

She also suggested that it might be used by people who, for whatever reason, just "do not want to take a daily pill or injections," and/or those who prefer a non-oral "on demand" method for periods when they are sexually active.

The pill is also "discrete," said Riddler, who noted it "could easily fit in a pocket."

The findings were presented Tuesday at the Conference on Retroviruses and Opportunistic Infections, in Seattle. Such research is considered preliminary until published in a peer-reviewed journal.

[Dr. Michael Horberg](#) is director of HIV/AIDS and STD with the Kaiser Permanente and Care Management Institute in Rockville, Md.

He said he thinks the new pill "could have potential for success."

"Of course, for many, oral medications may be preferable," said Horberg. "But to have effective options for HIV prevention, you need more than one option. So, yes, this could be effective."

The overriding concern, he stressed, is that people choose a prevention option they will feel comfortable using and consistently take according to instructions. Because no matter the method of prevention, he said, "they only work if they are used."

More information: There's more on PrEP at the [U.S. Centers for Disease Control and Prevention](#).

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