Rectal Microbicide Shows Better Safety in Laboratory Study

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Laboratory testing of a modified version of the Viread (tenofovir) microbicide gel provides further evidence that it may be safe for rectal use, according to a paper published online ahead of print by the Journal of Antimicrobial Chemotherapy.

The encouraging results contribute to a better understanding of the gel's tolerability, already evident in preliminary findings from a 65-person Phase I clinical trial reported at the 19th Conference on Retroviruses and Opportunistic Infections earlier this year in Seattle.

"The lining of the rectum is much more fragile than the vaginal epithelium, so we can't be certain a product like tenofovir gel that is safe for vaginal use will be completely safe to use in the rectum," said lead study author Charlene Dezzutti, PhD, of the University of Pittsburgh School of Medicine and the Microbicide Trials Network (MTN) in an accompanying news announcement. "We are very encouraged by our laboratory data that suggest the reformulated gel could be safer for rectal use, and serve as a dual compartment gel for use in both the vagina and rectum."

The tenofovir gel that has been explored for vaginal use is hyperosmolar—it contains higher concentrations of sugars and salts, compared with those inside the cells of the rectum, which can cause the cells to expel too much water. Not only can this result in side effects, such as cramping and diarrhea, but it can actually increase the chances of HIV infection during anal intercourse.

To make the tenofovir gel more amenable to rectal use, researchers from CONRAD, a research organization that holds the rights to develop the gel, reformulated it with a reduced amount of glycerin, a common additive found in many gel-like products.

The laboratory evaluations conducted by Dezzutti and her colleagues indicate that the reformulated gel was three times less likely to cause cells in rectal tissue to release water and was equally effective against HIV as the vaginal formulation.

In the MTN-007 clinical trial presented at CROI, investigators noted lower rates of abdominal pain, urgent defecation, bloating, nausea and diarrhea among study volunteers who used the modified gel compared with those using the original formulation of the microbicide in an earlier trial.

When asked about the likelihood that they would use the gel in the future, 87 percent of the

participants who used the rectal formulation of tenofovir gel indicated they would likely use the gel again, compared with 93 percent of the placebo gel group and 63 percent of those using rectal applications of a gel containing nonoxynol-9.

As a follow-up to MTN-007 and the laboratory data reported by Dezzutti and her colleagues, the federally funded MTN plans to conduct MTN-017, a Phase II clinical trial that will enroll nearly 200 men who have sex with men and transgender women in South Africa, Peru, Thailand and the United States.

Three regimens will be explored in the trial: Daily use of the rectal tenofovir gel, as-needed use of the gel (inserted before and after anal intercourse) and Truvada (tenofovir plus emtricitabine) taken orally every day.

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