

Gel safe and acceptable as approach to preventing HIV from anal sex

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A reformulated version of an anti-HIV gel developed for vaginal use was found safe and acceptable by HIV-negative men and women who used it rectally, according to a Phase I clinical trial published today in *PLOS ONE*. The study, led by researchers with the U.S. National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN), tested a reduced glycerin formulation of tenofovir gel, and has spurred the development of an expanded safety study of the gel, expected to launch later this year.

Rectal microbicides, [gel](#)-based antiretroviral products applied into the rectum with the use of an applicator, are being developed as an approach for preventing or reducing the [sexual transmission](#) of HIV from unprotected anal sex. Researchers are working on developing rectal-specific products as well as reformulations of vaginal products, specifically, [tenofovir](#) gel.

The study, known as MTN-007, was the first to evaluate tenofovir gel reformulated with less [glycerin](#), a common additive found in many gel-like products, in the hopes of making it better suited for use in the rectum. It began in October 2010 and enrolled 65 men and women at three sites – the University of Pittsburgh, University of Alabama at Birmingham and Fenway Health in Boston.

In MTN-007, study participants were randomly assigned to one of four study groups. Three of these groups were assigned to use one of the following products for a one-week period: a reduced glycerin formulation of tenofovir gel; a placebo gel containing no [active ingredient](#); or a gel containing the spermicide nonoxynol-9. A fourth group did not use any gel but took part in all of the study-related procedures and tests, including physical and rectal exams.

Study results, preliminarily presented at a scientific meeting in 2012, indicated no significant differences in [side effects](#) among the three gel

groups. Eighty percent of participants reported minor side effects related to the use of study products, and 18 percent reported moderate side effects. (Two study participants reported severe adverse events, but they were not related to use of the study products.) Participants' adherence to the use of their assigned study products was high, with 94 percent using the products daily as directed. When asked about the likelihood that they would use the gel in the future, 87 percent of the participants who used the reformulated gel indicated they would likely use the gel again, compared to 93 percent of the placebo gel group, and 63 percent of the nonoxynol-9 gel group. In addition to assessing safety and acceptability, researchers also conducted gene expression testing, and noted changes in the activation of some genes in the reduced glycerin tenofovir gel group, which they will continue to assess in future rectal microbicide studies.

"We are very encouraged that the reformulated gel was quite safe, and that most people who used it said they would be willing to use it in the future," said Ian McGowan, M.D., Ph.D., co-principal investigator of the MTN and professor of medicine, Division of Gastroenterology, Hepatology and Nutrition and Department of Obstetrics, Gynecology and Reproductive Sciences, University of Pittsburgh School of Medicine. "These results have formed the basis for a follow-up study that should provide us with even more detailed information about the safety and acceptability of the gel."

Researchers are now in the final planning stages of a Phase II, multi-site trial of the reformulated gel called MTN-017 that will involve 186 men who have sex with men and transgender women at clinical sites in Peru, South Africa, Thailand, and the U.S., including Puerto Rico. Participants will cycle through three study regimens: reformulated tenofovir gel used daily, reformulated tenofovir gel used before and after anal sex, and daily use of the antiretroviral tablet Truvada®. MTN-017 will allow

researchers to collect additional information about the gel's safety and acceptability in the rectum, and compare it to the use of Truvada.

Provided by Microbicide Trials Network

In addition to Dr. McGowan, other authors of the study include Craig Hoesley, M.D., University of Alabama; Ross Cranston, M.D., University of Pittsburgh; Philip Andrew, FHI 360; Laura Janocko, Ph.D., MTN and Magee-Womens Research Institute; James Dai, Fred Hutchinson Cancer Research Center; Alex Carballo-Diequez, Ph.D., Columbia University; Ratiya Kunjara Na Ayudhya, BSMT, MTN; Jeanna Piper, M.D., Division of AIDS, National Institute of Allergy and Infectious Diseases; Florian Hladik, M.D., Ph.D., Fred Hutchinson Cancer Research Center; and Ken Mayer, M.D., Fenway Health.

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CONRAD developed the reduced glycerin formulation of tenofovir gel evaluated in MTN-007 and it differs from the formulation originally developed for vaginal use. Although the vaginal gel produced a significant antiviral effect when used in the rectum, it was found to cause gastrointestinal side effects in some study participants in an earlier study called RMP-02/MTN-006.

The vaginal formulation of tenofovir gel continues to be evaluated for preventing the [transmission of HIV](#) through vaginal sex in women. Ongoing is a Phase III trial called FACTS 001 that is testing its use before and after sex among women in South Africa. FACTS 001 hopes to replicate the results of CAPRISA 004, which found this regimen reduced the risk of HIV by 39 percent compared to placebo gel. The VOICE Study (Vaginal and Oral Interventions to Control the Epidemic), however, found daily use of the gel not effective among its [study participants](#); most of the women did not use the product daily as recommended.

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