

International study finds rectal microbicide gel safe when used daily and with sex

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A reduced glycerin formulation of tenofovir gel was found safe when used daily and around the time of sex, according to the first extended safety study of a rectal microbicide for HIV prevention from anal sex. Presented today at the 23rd Conference on Retroviruses and Opportunistic Infections (CROI 2016), the study, led by the U.S. National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN), also indicated that participants were as likely to follow through using the gel with sex as they were to using daily oral pre-exposure prophylaxis (PrEP) - a prevention strategy in which people who are HIV-uninfected take a daily pill to reduce their risk of infection.

The Phase II study, MTN-017, began in September 2013 and enrolled 195 men who have [sex](#) with men (MSM) and transgender women at sites in Peru, Thailand, South Africa and the United States, including Puerto Rico. MTN-017 participants - 12 percent of whom were transgender women - cycled through three study regimens which each lasted eight weeks: reduced glycerin [tenofovir gel](#) used daily, reduced glycerin tenofovir gel used before and after anal sex, and daily use of the antiretroviral tablet Truvada (emtricitabine/tenofovir disoproxil fumarate), developed by Gilead Sciences, Inc. This design allowed researchers to collect information about the gel's safety and acceptability in the rectum, and compare it to the use of oral Truvada, which was approved for use as PrEP by the U.S. Food and Drug Administration in 2012.

Most side effects from study products in MTN-017 were minor,

indicating the gel was safe, and there were no significant differences in adverse events among the gel regimens compared to oral Truvada. Overall, participants were highly adherent in MTN-017, with most following through in using their assigned products 80 percent of the time or more. Participants were similarly adherent to using gel before and after sex (93 percent) as they were to taking daily oral Truvada (94 percent). They were less adherent, however, when using the gel on a daily basis (83 percent). Adherence in MTN-017 was measured by a combination of responses to daily questions sent by text message, number of returned gel applicators and blood tests to confirm the presence or absence of drug.

When asked about preferences, participants reported they preferred oral Truvada to the gel, but found the before and after sex gel regimen as easy to use as oral Truvada. When asked about the likelihood that they would use the study products in the future, participants said that they would be as likely to use the gel before and after sex as they would to take oral Truvada. Forthcoming analyses from MTN-017 will shed light on how much drug was absorbed in the blood, rectal fluid and tissue, and assess whether use of the products caused changes in cells or tissue.

"The results from MTN-017 demonstrate there is a place for rectal microbicides used around the time of sex in future HIV prevention efforts," said Ross D. Cranston, M.D., associate professor, University of Pittsburgh School of Medicine, who led the study with Javier R. Lama, M.D., M.P.H., investigator and director, HIV Prevention Intervention Studies, IMPACTA PERU Clinical Trials Unit, Lima, Peru. "While we have more to learn from ongoing analyses of tissue and blood testing, the completion of this study was a significant undertaking and represents a major step forward in the development of a rectal microbicide for people at risk of HIV from anal sex."

MTN-017 was a larger follow-up trial to a previous study, MTN-007,

that found the reduced glycerin formulation of tenofovir gel was safe and acceptable to both men and women who used it in the rectum daily for a one-week period. The gel used in both studies was formulated with less glycerin to address gastrointestinal side effects experienced by some study participants who used an original vaginal formulation of tenofovir [gel](#) in an early study called RMP-02/MTN-006.

"The MTN-017 findings come at a pivotal time in the field of rectal microbicides, setting the stage for future studies and complementing ongoing research into new products and delivery methods," said Ian McGowan, M.D., Ph.D., 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. "Research is already underway at MTN to expand the pipeline of rectal microbicide products in order to find the right product to move forward into an effectiveness study."

Globally, racial and ethnic minorities, MSM and transgender women are disproportionately affected by HIV. Although most microbicide research has focused on products for vaginal use, the risk of becoming infected with HIV from unprotected anal sex may be 20 times greater than unprotected vaginal sex, in part because the rectal lining is only one-cell thick compared to the vagina's multiple layers.

Provided by Microbicide Trials Network

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