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International study finds high levels of adherence to use of rectal microbicide gel

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Participants enrolled in a rectal microbicide study were just as likely to follow through using an anti-HIV gel with anal sex as they were to using daily oral pre-exposure prophylaxis (PrEP), according to adherence results presented today at the HIV Research for Prevention conference. The study, led by the U.S. National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN), was the first extended safety study of a rectal microbicide for prevention of HIV infection from anal sex, which initially reported that the gel was safe in February 2016.

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) as PrEP, developed by Gilead Sciences, Inc.

Researchers found that most participants were highly adherent during the course of MTN-017, using study 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 when using the gel on a daily basis (83 percent).

"Overall adherence to the three regimens in MTN-017 was high," said

Alex Carballo-Diéguez, Ph.D., HIVR4P abstract co-author and professor of medical psychology, Columbia University. "What we found most remarkable was that even though efficacy of the gel has not been established, its adherence was similar to oral Truvada, which we know is effective. This tells us that rectal microbicide gels, provided they are proven effective, could be a potential alternative for people who don't want to use daily oral PrEP."

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. Throughout the study, researchers employed real-time pharmacokinetics (PK), in which they regularly tested participants' blood to assess the presence of drug—a determinant of whether they were using their assigned study products—and shared the results with participants as part of their adherence counseling sessions. These sessions also included convergence interviews, collaborative conversations to engage participants and clarify discrepancies among adherence measures.

In a related HIVR4P poster session (P24.11), Iván C. Balán, Ph.D., assistant professor of clinical psychology, Columbia University, found that convergence interviews conducted in MTN-017, which were aimed at improving the accuracy of adherence data, were feasible and acceptable to both adherence counselors and study participants. They also provided important context to understanding discrepancies in product use assessments and PK results. Engaging study participants as allies in the process was critical to avoid making them feel confronted and thus becoming defensive, noted Dr. Balán.

Provided by Microbicide Trials Network

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