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BACKGROUNDER

MTN-035 (DESIRE)

Acceptability, Tolerability and Adherence to Three Rectal Microbicide Placebo Methods

What is DESIRE?

- MTN-035, or DESIRE (Developing and Evaluating Short-acting Innovations for Rectal Use), is an open label crossover study to systematically examine multiple placebo methods for delivering drugs to help prevent HIV from anal sex. The study will include approximately 210 HIV-negative cisgender men, transgender men and transgender women who have sex with men at sites in Malawi, Peru, South Africa, Thailand and the United States. Results of the study, anticipated in 2020, will impact the development of intervention strategies for future rectal microbicide drug trials.

- MTN-035 is a study of the Microbicide Trials Network (MTN), an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. The protocol chair for the study is José A. Bauermeister, Ph.D., M.P.H., of the University of Pennsylvania School of Nursing.

- Methods being tested in MTN-035 include a placebo douche, a placebo suppository and a placebo insert (fast-dissolving tablet inserted into the rectum). The placebo insert used in the study was developed by CONRAD, a not-for-profit research and development organization located in Arlington, Va.

- During MTN-035, study participants will be asked about their preferences and the likelihood that they would use the approaches if effective and available. Researchers will also assess the safety of each method and evaluate whether participants use them correctly and consistently.

- MTN-035 is part of a research agenda at the MTN focused on the development of HIV prevention products for men and women who engage in condomless anal sex, a major risk factor for HIV infection.

Why is DESIRE Important?

Microbicides are products applied inside the vagina or rectum being developed and tested to provide protection against HIV infection from sex. Products currently being tested in clinical trials contain antiretroviral (ARV) drugs, many of which are commonly used to treat people with HIV. Although most microbicide research has focused on products to prevent HIV infection associated with vaginal sex, important strides are being made in addressing the need for rectal microbicides.

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Anal sex is a common sexual behavior practiced by cisgender and transgender men and women around the world. According to some estimates, the risk of becoming infected with HIV during anal sex is 20 times greater than vaginal sex because the rectal lining is thinner and more fragile than the vaginal lining. While condoms are an effective method to prevent HIV infection through anal sex, many people can't or don't want to use them every time they have sex. Similarly, oral pre-exposure prophylaxis (PrEP) – an HIV prevention strategy in which people take a daily pill called Truvada® to prevent infection – has been shown to be highly effective, however, not all individuals vulnerable to HIV infection are willing or able to access it. Just as there are multiple contraception options for cisgender women who choose to prevent pregnancy, a rectal microbicide could give people who practice anal sex an additional choice for HIV prevention – one that is non-systemic and used around the time of sex.

MTN researchers reported results from the first Phase II study of a rectal microbicide, a gel containing the ARV tenofovir, in early 2016. The study, MTN-017, evaluated whether a reduced-glycerin formulation of tenofovir gel was safe and acceptable as a rectal microbicide. Results indicated that the gel used in MTN-017 was safe, with most study participants highly adherent to using it. The gel was found most acceptable when used around the time of sex, rather than daily. Some participants, however, expressed dissatisfaction with the gel delivery method, a plastic applicator, prompting researchers to continue to explore other formulations and delivery methods for rectal microbicides. The approach used in DESIRE will assess study participants' preference for a rectal delivery method before specific products have been developed, and, importantly, after they have had an opportunity to use it.

How DESIRE is Designed

MTN-035 is designed to evaluate the acceptability, tolerability and adherence to three placebo methods for delivering drugs to help prevent HIV infection from receptive anal sex. The study will enroll approximately 210 HIV-negative cisgender men and transgender men and transgender women who have sex with men. Study participants will use each rectal delivery method for a month at a time, with a week-long break between methods. They will be asked to use each method between 30 minutes and 3 hours prior to engaging in receptive anal sex, or once a week for participants who have not engaged in receptive anal sex in a given week.

Laboratory tests performed during the study will assess the safety of the methods, and behavioral assessments will be used to measure and evaluate participants' experience and comfort using them. Researchers will also evaluate whether participants used the delivery methods correctly and consistently.

As part of the study, all participants will receive HIV risk reduction counseling and condoms and will be tested for HIV and sexually transmitted infections.

Methods Being Studied in DESIRE

The delivery methods included in MTN-035 are a placebo insert (a fast-dissolving rectal tablet) approximately two-thirds of an inch in length; a placebo suppository approximately an inch and a half in length; and a commercially-available 120 mL douche bottle that participants will be instructed to fill with clean tap or bottled water prior to insertion. The placebo insert was developed by CONRAD, a not-for-profit research and development organization located in Arlington, Va.

Where DESIRE is Being Conducted

MTN-035 is being conducted at the following trial sites, pending necessary approvals: the Blantyre Clinical Research Site (CRS) in Malawi; the IMPACTA CRS in Lima, Peru; the Wits Reproductive Health and HIV Institute in Johannesburg, South Africa; the Chiang Mai University HIV Prevention CRS in Thailand; and, the University of Pittsburgh CRS; the Bridge HIV CRS in San Francisco and the University of Alabama at Birmingham CRS in the United States.

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About the Microbicide Trials Network

The Microbicide Trials Network (MTN) is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. Based at Magee-Womens Research Institute and the University of Pittsburgh, the MTN brings together international investigators and community and industry partners whose work is focused on the rigorous evaluation of promising microbicides – products applied inside the vagina or rectum that are intended to prevent the sexual transmission of HIV – from the earliest phases of clinical study to large-scale trials that support potential licensure of these products for widespread use. More information about the MTN is available at https://mtnstopshiv.org.

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