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MICROBICIDE TRIALS NETWORK BACKGROUND

MTN-015:

An Observational Study of Women Who Acquire HIV While Participating in a Microbicide Trials Network Clinical Trial

Study Overview

MTN-015 is a long-term, observational study that seeks to understand the nature of HIV progression and treatment response in HIV-positive women who may have been using a topical microbicide or oral antiretroviral therapy as pre-exposure prophylaxis (PrEP) at the time they were infected. Microbicides are substances designed to prevent the sexual transmission of HIV and other sexually transmitted infections when applied topically to the vagina or rectum; PrEP typically involves the daily use of oral antiretroviral therapy (ART) to prevent HIV infection. Currently, there is little information about the short- and long-term consequences for women who may have been using either type of prevention strategy at the time of infection. This study will provide new insight and important information about the potential advantages or risks of these strategies, and will be critical to efforts focused on developing microbicides and other HIV prevention approaches for high-risk populations.

MTN-015 is being conducted by the Microbicide Trials Network (MTN), a clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH).

How the Study is Being Conducted

In order to reduce the risk of acquiring HIV for women participating in its trials, MTN researchers provide free condoms, HIV testing and HIV risk-reduction counseling for all participants, as well as routine testing and treatment for sexually transmitted infections. Despite these intensive efforts, some trial participants will become infected with HIV. In such cases, women are counseled by MTN study staff and referred to services at local facilities that provide medical care and treatment, including ART, as well as psychological and social support. These services may be available within the same health care facility that houses the research site, with a program funded by the U.S. President's Emergency Plan for AIDS Relief through arrangements made by MTN site investigators or with another health care provider.

Women who acquire HIV infection during an MTN clinical trial will be invited to participate in MTN-015. As part of the study, they make frequent visits to the research site for physical exams and laboratory tests that help researchers assess how the disease is progressing and how the women are responding to treatment. Specifically, researchers closely monitor levels of HIV in the blood (HIV viral load), extent of damage to cells in the immune system (CD4+ T-cell count), virologic response to therapy and other health indicators to determine if there are any differences among women who had been using either an active microbicide or an oral drug at the time of infection compared with women who were assigned to a trial control group.

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Although MTN-015 does not provide HIV treatment as part of the study, with a participant's permission, MTN-015 researchers maintain close contact with her primary treatment provider and share results of laboratory tests that are performed as part of the study, which may suggest modifications to her treatment and help improve the level of care. Researchers plan to follow women until 2013, at which time the study period may be extended.

Why this Study is Important

Microbicides represent one of the most promising HIV prevention approaches, especially for women, who, according to statistics from UNAIDS and the U.S. Centers for Disease Control and Prevention, represent nearly half (48 percent) of the 39.5 million people living with HIV/AIDS worldwide. Between 70 and 90 percent of all HIV infections in women are due to heterosexual intercourse. Moreover, due to both biological and cultural factors, women are more than twice as likely as their male partners to acquire HIV through sexual intercourse. Although correct and consistent use of male condoms has been shown to prevent HIV infection, women often cannot negotiate condom use with their male partners.

Clinical trials of different candidate microbicides will be necessary if a safe and effective product is to be identified, and many of these trials must be conducted in parts of the world where women are at high risk of acquiring HIV infection, despite intensive counseling on risk reduction methods. As such, it can be expected that some study participants will become infected with HIV while participating in a trial. Yet, the impact that candidate products may have on the natural history of HIV or its clinical course is not known. Long-term monitoring of women who become infected while participating in trials of microbicides or PrEP regimens will help researchers address important questions about the risk of HIV drug resistance with these products. Short of speculation, no information currently exists about either the potential for or incidence of HIV drug resistance among participants in microbicide or PrEP trials.

Funding

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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 (NIAID), part of the U.S. National Institutes of Health (NIH). The MTN brings together international investigators and community and industry partners who are devoted to reducing the sexual transmission of HIV through the development and evaluation of microbicides, working within a unique infrastructure specifically designed to facilitate research required to support licensure of topical microbicide products for widespread use. In order to face the global urgency of the HIV/AIDS epidemic head-on, the MTN will implement a broad portfolio of clinical trials in Africa, India and the United States between 2006 and 2013. Many of these trials are focused on assessing antiretroviral-based microbicides and include studies designed to evaluate microbicides along with other promising HIV prevention approaches, such as oral antiretroviral prophylaxis.

Based at the University of Pittsburgh and Magee-Womens Research Institute in Pittsburgh, Pennsylvania, U.S.A., the MTN is directed by Sharon Hillier, Ph.D., principal investigator. MTN's core operations are supported by a network laboratory at the University of Pittsburgh, a statistical and data management center housed within the Statistical Center for HIV/AIDS Research & Prevention at the Fred Hutchinson Cancer Research Center, and Family Health International, a global organization with expertise conducting clinical protocols. It receives its funding from three NIH institutes: NIAID, the National Institute of Mental Health and the National Institute of Child Health and Human Development. Among the principals developing and evaluating microbicides for HIV prevention globally, the MTN is the only one funded by the NIH. More information about the MTN and MTN 015 is available at www.mtnstopshiv.org.

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