

## Anti-HIV gel being evaluated in pregnant and breastfeeding women

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Determining whether a promising HIV prevention gel is safe for women to use while they are pregnant or breastfeeding is the aim of a new clinical trial being conducted by the National Institutes of Health-funded Microbicide Trials Network (MTN). Researchers are hopeful that the study -- the first clinical trial of the vaginal microbicide tenofovir gel in breastfeeding women and only the second in pregnant women -- will bring them a step closer to developing a safe and effective HIV prevention product women can use throughout their lives.

The Phase I trial is underway at two U.S. sites -- Magee-Womens Hospital of the University of Pittsburgh Medical Center and the University of Alabama, Birmingham (UAB) -- but has implications for women throughout the globe. Indeed, nearly 16 million women are living with HIV worldwide, with most acquiring infection through unprotected [vaginal sex](#). Microbicides, such as [tenofovir gel](#), are products being developed to prevent HIV infection when used in the vagina or rectum. Researchers anticipate tenofovir gel may be the first vaginal microbicide approved for preventing HIV infection in women.

"Tenofovir gel and other vaginal microbicides under development are intended to be used by sexually active women -- the very women most likely to get pregnant -- yet we have very little information about whether these products are safe for them to use," said Richard Beigi, M.D., M.Sc., assistant professor of obstetrics, gynecology and [reproductive sciences](#) at the University of Pittsburgh School of Medicine, who is leading the study.

"In fact, HIV prevention may be most critical during pregnancy due to heightened immune responses or [hormonal changes](#) that appear to make [pregnant women](#) twice as likely to be infected by [sexual partners](#). Most women also continue to be sexually active and use medication while they are pregnant and breastfeeding, so we need to know if products like tenofovir gel are safe for women and their babies before they become widely available," he added.

Promising results from an earlier clinical study of tenofovir gel called CAPRISA 004 found 39 percent fewer infections among HIV-negative women who used it before and after vaginal sex compared to women who used a placebo gel. A major large-scale study being conducted by the MTN called VOICE -- Vaginal and Oral Interventions to Control the Epidemic, is currently testing whether daily use of the gel, or an antiretroviral (ARV) tablet, can reduce risk for HIV among 5,000 women in southern Africa. The U.S. Food and Drug Administration (FDA) has indicated it will consider approving tenofovir gel as an [HIV prevention](#) method for women based primarily on its review of the results of CAPRISA 004 and VOICE, which are expected in 2013.

The new study, MTN-008, will provide critical information about the safety of using tenofovir gel during pregnancy and lactation, which the FDA also considers essential to its decision whether to approve the gel. The study is part of a comprehensive research program at the MTN designed to take incremental steps toward determining whether tenofovir gel can safely and effectively protect women against [HIV infection](#) when they are pregnant or breastfeeding.

Tenofovir gel contains the same ARV drug that in oral tablet form is a mainstay of one of the most widely used regimens for treating HIV. Oral tenofovir is increasingly being used, along with other ARVs, to safely treat both pregnant and breastfeeding women who are HIV-positive. Research also has shown that HIV-positive pregnant women who are

treated with oral tenofovir pass very little drug to their newborn infants.

MTN-008 is a follow-up study to MTN-002, which found that a single dose of tenofovir gel given to pregnant women hours before scheduled Cesarean delivery was safe and well-tolerated by both mother and infant, resulting in only trace amounts of active drug in the mother's bloodstream, and in the amniotic fluid and umbilical cord blood. The drug levels measured in umbilical cord blood were 40 times lower than drug levels in studies of HIV-infected women who took the tablet form of tenofovir while they were pregnant. Building on these results, MTN-008 will test daily use of tenofovir gel by pregnant women for one week during third trimester pregnancy, and daily use of the gel for one week by breastfeeding mothers four to 26 weeks after they have given birth.

"By taking a cautious, step-wise approach to this research, we are ensuring the safety of both mothers and their infants," said Dr. Beigi. "Our overall goal is to find a product that women can safely use to protect against HIV during all stages of pregnancy and motherhood."

Researchers will enroll approximately 105 HIV-negative mother-infant pairs. For the pregnancy group, researchers will initially enroll 45 women between 37 and 39 weeks gestation and randomize them to receive tenofovir gel or a placebo gel. The women will apply one dose of their assigned study product (tenofovir gel or placebo gel) for seven consecutive days and undergo evaluation for side effects. Provided there are no safety concerns, researchers will then enroll a second group of 45 pregnant women who will follow the same seven-day regimen. The second group of women will enter the study earlier in their third trimester -- between 34 and 36 weeks gestation. For the group of breastfeeding women, all 15 participants who are enrolled will use tenofovir gel daily for seven days.

The researchers plan to evaluate the safety of the drug and assess how much active drug is absorbed during pregnancy and subsequently transferred to the fetus. In breastfeeding mothers, the researchers will also measure drug levels in breast milk and assess whether the drug is transferred to the baby. Depending on results of the study, which are expected in late 2012, the researchers will likely embark on a larger international trial involving a greater number of pregnant women, including those at earlier gestational ages.

Provided by Microbicide Trials Network

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