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Anti-HIV gel proven safe, tolerable for women

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An experimental anti-HIV gel is safe for women to use on a daily basis, according to researchers at the University of Alabama at Birmingham (UAB) and the University of Pittsburgh School of Medicine.

Testing showed the gel, called tenofovir, was favorably self-applied and tolerable to non-HIV-infected women, a significant boost to HIV and AIDS prevention efforts focused on next-generation microbicides to reduce infection rates, the researchers said.

The women study participants said if tenofovir gel is approved for the prevention of HIV infection, they would be willing to apply the gel to themselves daily or before sex, whichever is determined the best use.

“The gel is safe to use, and well tolerated by HIV-negative women. That’s a key message in our findings,” said Craig Hoesley, M.D., associate professor in the UAB Division of Infectious Diseases and author on the initial Phase II results. “This sets the stage for larger studies to see if tenofovir can prevent HIV infection.”

The tenofovir Phase II trial results were presented Monday, Feb. 25 at an international microbicides meeting in New Delhi, India. The researchers are part of the U.S. National Institutes of Health-funded Microbicide Trials Network, an international team of researchers devoted to exploring and evaluating anti-HIV microbicides.

“Based on what we have learned we can proceed with greater confidence

on a path that will answer whether tenofovir gel and other gels with HIV-specific compounds will be able to prevent sexual transmission of HIV in women when other approaches have failed to do so," said Sharon L. Hillier, Ph.D., director of reproductive infectious disease research at the University of Pittsburgh School of Medicine and principal investigator on the Phase II study.

Researchers evaluated if tenofovir was safe to use every day for six months, or safe to use prior to each act of intercourse. They found both approaches equally safe. Women in the study were asked to use condoms in addition to the gel.

The researchers found no disruption of liver, blood or kidney function in each group of women using a different gel regimen, including those given a placebo gel that looked and felt identical to the tenofovir gel.

The study included 200 sexually active HIV-negative women enrolled at UAB, Bronx-Lebanon Hospital Center in New York and the National AIDS Research Institute in Pune, India. Participants were age 19 to 50, and 64 percent were married.

In addition to the safety findings, the researchers found a significant willingness by women to follow the anti-HIV treatment guidelines. Eighty percent of the women instructed to use the gel within two hours of having sex said they followed instructions, and 83 percent instructed to use the gel daily said they had done so in the week prior.

Hoesley said if the gel were approved to help prevent HIV infection, more than 90 percent of the study volunteers said they would seriously consider using it, regardless of the regimen, to protect their sexual health.

"We asked women 'How acceptable is this as a prevention option, is it

too messy, is it a nuisance, and will you use it?' Our study showed they will use it and they're not bothered by the gel," Hoesley said.

The active ingredient in tenofovir gel is a class of anti-retroviral drugs called nucleotide reverse transcriptase inhibitors, which act against HIV by blocking the virus' ability to replicate and grow inside the body.

Source: University of Alabama at Birmingham