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Herpes medication does not reduce risk of HIV infection in individuals with HSV-2

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An international clinical trial has found that acyclovir, a common medication for treating herpes simplex virus-2 (HSV-2), the most common cause of genital herpes, does not reduce the risk of HIV infection when taken by people infected with HSV-2. Multiple studies have shown that people with HSV-2 have a higher risk of acquiring HIV.

Researchers had hoped that acyclovir's ability to suppress the herpes virus, and its associated genital sores and breaks in the skin, could cut down on the likelihood of HIV being transmitted to a person with HSV-2 during sexual intercourse.

The Phase III clinical trial was led by the University of Washington in Seattle, in coordination with the HIV Prevention Trials Network, an international consortium funded by the National Institute of Allergy and Infectious Diseases (NIAID) in the National Institutes of Health. The findings were presented this week at the Conference on Retroviruses and Opportunistic Infections in Boston.

"The study was successful in answering the question of whether acyclovir could cut down on the risk of HIV acquisition for people infected with HSV-2," explained Dr. Connie Celum, the leader of the study and a UW professor of global health and medicine in the Division of Allergy and Infectious Disease and director of the International Clinical Research Center in the UW Department of Global Health. "We were hopeful that acyclovir would help reduce HIV acquisition in people with HSV-2. Though the study did not find that acyclovir helped with

HIV acquisition, we did find that it reduced genital ulcers associated with HSV-2. Now we need to continue our research on the mechanisms through which HSV-2 acts as a risk factor for HIV, and how we might be able to use that knowledge to reduce the spread of HIV."

HSV-2 is one of the most common sexually transmitted infections worldwide and is especially prevalent in areas with high rates of HIV infection. Most people who are infected with HSV-2 do not know they have the virus because symptoms can be mild or absent. In some infected individuals, the virus can produce recurring genital herpes, a condition characterized by sores and breaks in the skin of the genital region. An active HSV-2 infection also attracts immune-system cells called CD-4 T-cells to the genital region, and HIV easily attaches to this type of cell. Multiple studies have shown that people with HSV-2 have a two-fold increase in their risk of acquiring HIV.

This study followed up on those results to test the theory that suppressing HSV-2 could cut down on HIV acquisition. It was launched in 2003, and with nine study sites in Peru, South Africa, Zambia, Zimbabwe, and the United States, it was the largest study yet of herpes suppression. There were 3,277 people with HSV-2 initially enrolled in the study, 105 people excluded, and 3,172 people included in the final analysis. Volunteers in Peru and the United States were HSV-2-infected men who have sex with men, and volunteers in Africa were HSV-2-infected women.

Half of the participants were randomly assigned to receive either a placebo or a standard daily dose of acyclovir, 400 mg twice a day. The study was double-blinded, meaning that neither participants nor care providers knew which treatment the participants were receiving. Both the placebo and treatment groups received standard HIV-prevention treatment, which includes being supplied with condoms and given extensive counseling on how to reduce the risk of HIV infection.

Researchers found that there was a 3.9 percent HIV incidence rate, a total of 75 cases, in participants who received acyclovir suppression, and a 3.3 percent HIV incidence rate, or 64 cases, in the placebo group. The difference between the groups was not statistically significant. The acyclovir treatment did succeed in reducing genital ulcers -- participants in the treatment group had a 37 percent reduction in genital ulcer incidence, and a significantly lower proportion of ulcers due to HSV-2.

"The study answered the scientific questions it was designed to answer," says Dr. Anna Wald, a UW professor of medicine and epidemiology who also helped lead the study. "The sites were able to recruit and retain a large number of volunteers, who maintained a high level of adherence to the twice-daily drug regimen. While we are disappointed with the results, the study was well-conducted and provides a clear answer about using acyclovir to reduce the risk of becoming HIV-infected."

The study participants have been informed of the findings and are being counseled on the continued need to avoid HIV exposure. Volunteers who became infected with HIV during the trial have been referred for appropriate medical care and treatment.

Source: University of Washington