Research shows progress toward a genital herpes vaccine

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An investigational vaccine protected some women against infection from one of the two types of herpes simplex viruses that cause genital herpes, according to findings in the *New England Journal of Medicine*.

The vaccine was partially effective at preventing herpes simplex virus type 1 (HSV-1), but did not protect women from herpes simplex virus type 2 (HSV-2). There were less than half of the cases of genital herpes caused by HSV-1 – 58 percent fewer -- in women who received the investigational vaccine compared to women who received the control vaccine.

"There is some very good news in our findings. We were partially successful against half of the equation – protecting women from genital disease caused by HSV-1," said Robert Belshe, M.D., director of the Saint Louis University Center for Vaccine Development and lead author of the study.

"It's a big step along the path to creating an effective vaccine that protects against genital disease caused by herpes infection. It points us in the direction to work toward making a vaccine that works on both herpes simplex viruses."

Both HSV-1 and HSV-2 are members of the herpesvirus family. Typically, HSV-2 causes lesions and blisters in the genital area. HSV-1 generally causes sores in the mouth and lips, although it increasingly has been found to cause genital disease.

There currently is no cure or approved vaccine to prevent genital herpes infection, which affects about 25 percent of women in the United States and is one of the most common communicable diseases. Once inside the body, HSV remains there permanently. The virus can cause severe neurological disease and even death in infants born to women who are infected with HSV and the virus is a risk factor for sexual transmission of HIV.

The clinical trial of an investigational genital herpes vaccine was funded by the National Institute of Allergy and Infectious Diseases (NIAID), which is part of the National Institutes of Health, along with GlaxoSmithKline (GSK), and conducted at 50 sites in the U.S. and Canada.

The study enrolled 8,323 women between ages 18 and 30 who did not have HSV-1 or HSV-2 infection at the start of the study. They were randomly assigned to receive either three doses of the investigational HSV vaccine that was developed by GSK or a hepatitis A vaccine, which was the control.

Participants were followed for 20 months and evaluated carefully for occurrence of genital herpes disease. In addition, all study participants were given blood tests to determine if asymptomatic infection with HSV-1 or HSV-2 occurred during the trial. Researchers found that two or three doses of the investigational vaccine offered significant protection against genital herpes disease caused by HSV-1. However the vaccine did not protect women from genital disease caused by HSV-2.

"We were surprised by these findings," said Belshe, who also is a professor of infectious diseases and immunology at Saint Louis University School of Medicine. "We didn't expect the herpes vaccine to protect against one type of herpes simplex virus and not another. We also found it surprising that HSV-1 was a more common cause of genital

disease than was HSV-2."

HSV-1 infection has become an increasingly common cause of genital disease, likely because more couples are engaging in oral sex. HSV-1 and HSV-2 are spread by direct contact – mouth to mouth, mouth to genitals and genitals to genitals – even when the infected person shows no symptoms, Belshe added.

Researchers are conducting laboratory tests on serum obtained from study participants as they continue to study why the vaccine protected women from genital disease caused by HSV-1 and not HSV-2.

One hypothesis, Belshe said, is HSV-1 is more easily killed by antibodies than is HSV-2. This means that the vaccine antibodies might work better against HSV-1 and result in protection from HSV-1 but not HSV-2.

Earlier studies of the investigational herpes vaccines showed it protected against genital herpes disease in women who were not infected with HSV-1 or HSV-2, but whose sexual partners were known to have genital herpes. Researchers believe the reason for the different outcome in the most recent clinical trial could be related to the fact that different populations were studied. The women in the earlier studies may have been protected due to immunologic or behavioral factors not present in the later study.

"It's always important to confirm scientific findings in repeated studies, which is why we investigated the vaccine in a large, placebo controlled trial," Belshe said. "Our findings confirmed the validity of the scientific process. You've got to have good scientific evidence that something actually works."

Provided by Saint Louis University