Study finds genital herpes vaccine ineffective in women

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An experimental vaccine intended to prevent genital herpes disease in women, although generally safe and well-tolerated, proved ineffective when tested in the recently concluded clinical study known as the Herpevac Trial for Women.

The Phase 3 trial, sponsored by GlaxoSmithKline (GSK) Biologicals, based in Belgium, with support from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, began in 2002. A total of 8,323 women aged 18-30 years participated in the trial at 50 sites in the United States and Canada. At the time of their enrollment, the study participants were free of the two types of herpes simplex viruses (HSV), HSV-1 and HSV-2.

Participants in the Herpevac trial were randomly divided into two groups. One group received the candidate vaccine, containing HSV protein along with an adjuvant intended to boost immune responses. The second, control group received a version of Havrix, a licensed vaccine against hepatitis A. This study design gave all participants the potential opportunity to be protected against either genital herpes or hepatitis A. GSK developed the candidate vaccine and also manufactures Havrix.

Each volunteer was vaccinated at the beginning of the study and again one and six months later. The participants were followed for 20 months after the initial injection and evaluated at each visit for HSV infection and genital herpes disease.

In two earlier studies involving men and women who did not have genital herpes but whose sexual partners were known to be infected, the candidate vaccine prevented genital herpes disease in more than 70 percent of the female volunteers who were free of HSV-1 and HSV-2 but had no clear effect in men. These studies formed the basis to conduct the larger Herpevac study in women only.

In the Herpevac study, however, the investigational vaccine was ineffective in protecting against genital herpes disease. The estimate of vaccine effectiveness was 20 percent, but all estimates have statistical uncertainty, and this effect was not substantially different from zero.

It is not known at this time why the vaccine proved ineffective, but the study collaborators continue to evaluate the trial data and intend to provide a more detailed analysis at a later date.

All the study investigators have been informed of the results. Study participants are being notified as to which vaccine they received, and those volunteers who received the candidate herpes vaccine are being offered Havrix.

HSV-1 and HSV-2, which cause cold sores and genital herpes disease, may be transmitted through sexual or other skin-to-skin contact, and can be spread even when the infected individual shows no symptoms. HSV can cause severe illness in infants born to HSV-infected women, and the virus has been identified as a risk factor for HIV transmission in adults. An estimated 1 in 4 women in the United States has genital herpes.

More information:
www.niaid.nih.gov/news/QA/pages/HerpevacQA.aspx