NIH launches trial of investigational genital herpes vaccine

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Researchers have launched an early-stage clinical trial of an investigational vaccine designed to prevent genital herpes disease. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, is sponsoring the Phase I trial, which is being conducted at the NIH Clinical Center in Bethesda, Md.

Genital herpes is one of the most common sexually transmitted infections in the United States. Most genital herpes cases are caused by infection with herpes simplex virus type 2 (HSV-2); however, herpes simplex virus type 1 (HSV-1) can also cause genital herpes. An estimated 776,000 people in the United States are infected with HSV-2 or HSV-1 each year. There is no vaccine to prevent genital herpes.

"Although genital herpes is treatable, it is a lifelong infection that can exact a substantial psychological and physical toll on infected individuals and places them at higher risk of acquiring HIV," said NIAID Director Anthony S. Fauci, M.D. "Furthermore, mothers with active genital herpes infection at time of delivery can transmit the virus to their newborns, which can lead to severe illness and death."

"A protective vaccine would help to reduce significantly the spread of this all-too- common sexually transmitted infection," Fauci added.

Led by principal investigator Lesia K. Dropulic, M.D., of NIAID's Laboratory of Infectious Diseases, the trial will test an investigational HSV-2 vaccine candidate, called HSV529, for safety and the ability to

generate an immune system response. The investigational vaccine manufactured by Sanofi Pasteur was developed by David Knipe, Ph.D., professor of microbiology and immunobiology at Harvard Medical School, Boston.

Preclinical testing of the candidate vaccine involved a 10-year collaborative effort between Dr. Knipe and Jeffrey Cohen, M.D., chief of NIAID's Laboratory of Infectious Diseases. The experimental product is a replication-defective vaccine, meaning that scientists have removed two key proteins from the vaccine virus so that it cannot multiply to cause genital herpes.

The clinical trial is expected to enroll 60 adults ages 18 to 40, who will be divided into three groups of 20 participants each. The first group will be of people who have been previously infected with HSV-2 and HSV-1 or solely with HSV-2; the second will have individuals who had been infected with HSV-1 only; and the third will consist of those who have not been infected with HSV-1 or HSV-2. The investigational vaccine is being tested among study participants who have previously been infected with HSV to determine if it may pose any safety issues.

Within each of the three groups, researchers will randomly assign participants to receive three doses (0.5 milliliters each) of the investigational HSV529 vaccine (15 participants) or a saline-based placebo vaccine (five participants). The three vaccinations will occur at study enrollment and again one month and six months later. Participant safety will be monitored throughout the course of the trial, and researchers will follow participants for six months after they have received their last dose of vaccine. Blood samples will be used to evaluate the candidate vaccine's ability to stimulate immune system responses to HSV-2, including production of virus-specific antibodies and T-cell responses. The study is expected to be completed by October 2016.

HSV-2 is generally transmitted through sexual contact and can spread even when the infected individual shows no symptoms. Although HSV-1 commonly infects the mouth and lips, it can also cause genital herpes. Once in the body, HSV migrates to nerve cells and remains there permanently, where it can reactivate to cause painful sores and blisters.

Provided by NIH/National Institute of Allergy and Infectious Diseases