

Vaccine for West Nile Virus enters human clinical trials

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A clinical trial of a new investigational vaccine designed to protect against West Nile Virus infection will be sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The experimental vaccine was discovered and developed by scientists at the Oregon National Primate Research Center at Oregon Health & Science University (OHSU) in Portland. The scientists were funded with a \$7.2 million grant from NIAID, awarded in 2009. The new vaccine is being tested in a Phase 1 clinical trial at Duke University in Durham, North Carolina, one of NIAID's Vaccine and Treatment Evaluation Units (VTEUs).

Most commonly spread through the bite of infected mosquitoes, West Nile Virus (WNV) infection is typically a seasonal epidemic in the United States that begins in late spring or early summer and continues into the fall. Last year, 2,205 cases of WNV disease and 97 related deaths were reported in the United States. The majority of people infected with WNV will show no symptoms. Roughly 1 in 5 people who are infected will display relatively mild symptoms, such as fever, headache, body aches, nausea, and vomiting. Only about 1 in 150 people infected with WNV will develop a serious neurologic illness, such as encephalitis or meningitis. Most people with WNV disease recover completely, but the elderly and other immunocompromised individuals are at higher risk for long-term side effects or death resulting from infection. From 1999 to 2014, a total of 41,762 cases of WNV disease have been confirmed in the United States, including 1,765 deaths. Although an effective veterinary vaccine against WNV is available, no

human vaccine has been approved for commercial use.

"Since first appearing in the United States in 1999, West Nile Virus has emerged as an important health threat in this country. NIAID is committed to research efforts to advance a preventive vaccine that could protect people against West Nile Virus infection," said NIAID Director Anthony S. Fauci, M.D.

The OHSU research team, led by senior scientist Mark Slifka, Ph.D., created the investigational vaccine, called HydroVax-001, with a novel, hydrogen peroxide-based process that renders the virus inactive while still maintaining key immune-system triggering surface structures. The virus used to make the vaccine is inactivated and cannot cause WNV infection. Because it is inactivated, the [experimental vaccine](#) likely could be used in a diverse population, including immunologically vulnerable groups, such as the elderly.

In preclinical studies, the test vaccine was effective at protecting mice against a lethal dose of West Nile Virus. In mice, the vaccine elicited neutralizing antibody responses and CD8+ T cells, which bind to and kill infected cells.

The clinical trial will test the safety of the vaccine as well as its ability to produce an immune response. The trial will enroll 50 healthy men and women, ages 18 to 50 years. The volunteers will be randomly assigned to receive a low dose of the vaccine (one microgram), a higher dose (four micrograms), or a placebo. Forty volunteers will receive the investigational [vaccine](#); 10 study volunteers will receive the placebo. Each participant will receive an intramuscular injection twice: on day one and on day 29. Study participants will be followed for 14 months.

The clinical trial is being conducted by researchers at Duke University, one of nine NIAID VTEUs. Enrollment is expected to be completed by

December 2015.

Provided by NIH/National Institute of Allergy and Infectious Diseases

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