NIAID DNA vaccine for H5N1 avian influenza enters human trial

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The first human trial of a DNA vaccine designed to prevent H5N1 avian influenza infection began on December 21, 2006, when the vaccine was administered to the first volunteer at the National Institutes of Health (NIH) Clinical Center in Bethesda, MD. Scientists from the Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), one of the NIH Institutes, designed the vaccine. The vaccine does not contain any infectious material from the influenza virus.

Unlike conventional flu vaccines, which are developed by growing the influenza virus in hens' eggs and then administered as a weakened or killed form of the virus, DNA-based vaccines contain only portions of the influenza virus' genetic material. Once inside the body, the DNA instructs human cells to make proteins that act as a vaccine against the virus.

VRC Director Gary Nabel, M.D., Ph.D., together with a team of scientists from the VRC recognized the potential for employing new vaccine technology against influenza, a disease for which effective vaccines have long been made, but for which the reliability of supply and manufacturing capacity has been problematic. Dr. Nabel and his colleagues previously have shown the DNA vaccine approach to be effective against influenza viruses in animal models, including highly pathogenic viruses such as the H5N1 strain and the H1N1 virus that caused the deadly 1918 pandemic. The DNA vaccine used in this study is similar to other investigational vaccines evaluated by the VRC that

hold promise for controlling other viruses, such as HIV, Ebola, SARS and West Nile.

"An effective H5N1 influenza vaccine would provide a potentially life-saving advance against a global health threat," notes NIAID Director Anthony S. Fauci, M.D. "More broadly, development of this DNA vaccine technology has the potential to improve our production capacity for vaccines to prevent seasonal influenza and other diseases."

"This influenza vaccine trial is further evidence of the ability of the NIAID Vaccine Research Center to rapidly translate basic research into potential products," he adds. "Our accelerated effort to understand and find new solutions to pandemic influenza is part of the NIAID commitment to respond to new emerging infectious disease threats and to improve public health preparedness."

Highly pathogenic avian influenza A viruses, specifically H5N1, have emerged in the past decade, causing widespread sickness and death in domestic and wild bird populations. As of December 27, 2006, 261 laboratory-confirmed human cases of H5N1 had been reported to the World Health Organization, resulting in death of more than half of infected individuals. While human cases remain relatively rare and are largely the result of direct virus transmission from infected birds, a few cases of human-to-human transmission have been reported. The severity of disease and the potential for human-to-human spread has provided a major incentive to accelerate developing a human vaccine for avian influenza.

With the spread of avian influenza virus, new strains have emerged, including clade II viruses in Indonesia and elsewhere that have drifted genetically from the initial strains detected in Southeast Asia. With this study, the investigators hope to learn whether new technologies, such as DNA vaccines, can provide protection against such viruses.

"This vaccine is aimed at newer strains of the H5N1 virus that currently pose a threat in Indonesia and represents an example of our ability to respond to shifting viruses with modern technology," says Dr. Nabel.

The study will enroll 45 volunteers between the ages of 18 and 60. Fifteen will receive placebo injections and 30 will receive three injections of the investigational vaccine over 2 months and will be followed for 1 year. Volunteers will not be exposed to influenza virus.

The vaccine contains no infectious material, and the virus was not present during any stage of the manufacturing process, notes Julie E. Martin, D.O., principal investigator of the study. "It is impossible for the vaccine to cause infection," she adds, "because it employs new technology known to safely stimulate broad immune responses." NIAID researchers will measure immune responses to the vaccine, assess its safety, and compare its potency to more traditional vaccine approaches.

Source: National Institute of Allergy and Infectious Diseases

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