NIH launches 2009 H1N1 influenza vaccine trials in HIV-infected pregnant women

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The first clinical trials to test whether the 2009 H1N1 influenza vaccine can safely elicit a protective immune response in pregnant women launched yesterday, and a trial to conduct the same test in HIV-infected children and youth will begin next week. The International Maternal Pediatric Adolescent AIDS Clinical Trials Group is conducting the studies, which are sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), both part of the National Institutes of Health.

"These studies are important because HIV infection and pregnancy both increase the risk for a poor immune response to the normal 15-microgram dose of seasonal influenza vaccine given to the general population," says NIAID Director Anthony S. Fauci, M.D. "Moreover, children, young people and pregnant women are at higher risk for more severe illness from the 2009 H1N1 influenza virus than other groups, and HIV-infected individuals in these populations may be particularly vulnerable."

"Because of the increased vulnerability of these populations, these trials are testing whether doses of licensed 2009 H1N1 influenza vaccine that are higher than doses being tested in other groups can safely elicit protective immune responses in HIV-infected children, youth and pregnant women," adds Lynne Mofenson, M.D., chief of the Pediatric, Adolescent and Maternal AIDS Branch in NICHD.

One trial will enroll 130 HIV-infected pregnant women ages 18 to 39 years who are in their second or third trimester (14 to 34 weeks) of pregnancy. The other trial will enroll 140 children and youth aged 4 to 24 years who were infected with HIV at birth.

Thirty-five sites and eight sub-sites across the United States and Puerto Rico are eligible to conduct the trials. Each volunteer will receive two 30-microgram doses of 2009 H1N1 influenza vaccine 21 days apart. (In contrast, the NIAID studies of 2009 H1N1 influenza vaccine in HIV-uninfected children, youth and pregnant women are testing doses of 15 and 30 micrograms.)

Safety data will be collected and monitored closely by the study investigators and an independent safety monitoring committee. The strength and longevity of the immune response elicited by the vaccine will be gauged in several ways.

The study team will take blood samples from the pregnant women after each dose and three and six months after delivery to measure the concentration of antibodies the women produce against 2009 H1N1 influenza virus and how strong that antibody response remains over time. After the women give birth, study staff will sample umbilical cord blood to measure the concentration of maternal antibodies against the H1N1 virus that were transferred to the infants through the placenta. The study team also will collect small blood samples from the infants at 3 and 6 months of age to measure their level of maternally derived antibody protection from the virus over time. The infants will not receive vaccine.

Similarly, in children and young people, the strength and longevity of the immune response will be gauged by testing blood samples taken 21 days after the first dose, 10 days after the second dose, and six months after entering the study.

The vaccine, manufactured by Novartis Vaccines and Diagnostics, contains inactivated 2009 H1N1 influenza virus, so it is impossible to become infected with the virus by receiving the vaccine. The vaccine does not contain adjuvant, a substance added to some vaccines to improve the body's response to vaccine.

Research on seasonal influenza vaccine and vaccines for other diseases in HIV-infected and other populations suggest that higher doses of vaccine tend to elicit stronger immune responses. These stronger responses, in turn, increase the concentration of protective antibodies in the bloodstream, which likely is beneficial to both the vaccinated individual and, if pregnant, to her fetus. This is the rationale for testing whether higher doses of licensed 2009 H1N1 influenza vaccine elicit a protective immune response in HIV-infected individuals and whether that protection is transferred to the fetuses of vaccinated pregnant women.

Source: NIH/National Institute of Allergy and Infectious Diseases (news : web)