Initial results show pregnant women mount strong immune response to one dose of 2009 H1N1 vaccine

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Healthy pregnant women mount a robust immune response following just one dose of 2009 H1N1 influenza vaccine, according to initial results from an ongoing clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health.

"For pregnant women, who are among the most vulnerable to serious health problems from 2009 H1N1 infection, these initial results are very reassuring," says NIAID Director Anthony S. Fauci, M.D. "The immune responses seen in these healthy pregnant women are comparable to those seen in healthy adults at the same time point after a single vaccination, and the vaccine has been well tolerated."

According to the Centers for Disease Control and Prevention, since the outbreak began last spring, at least 100 pregnant women have been hospitalized in intensive care units in the United States and at the last official count, 28 pregnant women have died.

A preliminary analysis of blood samples taken 21 days post-vaccination from a subgroup of 50 pregnant women participating in the trial shows the following:

In 25 women who received a single 15-microgram dose of the vaccine, the H1N1 flu vaccine elicited an immune response likely to be protective

in 92 percent, or 23 of 25, of these women.

In 25 women who received a single 30-microgram dose of the vaccine, the H1N1 flu vaccine elicited an immune response likely to be protective in 96 percent, or 24 of 25, of these women.

The trial began on Sept. 9 and reached its target enrollment of 120 volunteers in mid-October. All participants are between 18 to 39 years old and began the study in their second or third trimester (14 to 34 weeks) of pregnancy.

At entry into the study, the participants were divided at random into two groups: half are receiving two doses of a 15-microgram vaccine and the other half are receiving two doses of a 30-microgram vaccine. The two injections of vaccine are spaced three weeks apart.

Safety is being monitored closely in the trial, by the study investigators and by an independent panel of experts known as a safety monitoring committee. To date, the vaccine appears to be well-tolerated, and no safety concerns related to the vaccine have arisen.

The vaccine used in this clinical trial was manufactured by Sanofi Pasteur in its plant in Swiftwater, Pa., in the same manner as the company's injectable seasonal influenza vaccine. Like the seasonal flu vaccine, the 2009 H1N1 flu vaccine contains a purified portion of the killed virus and therefore cannot cause infection. The vaccine does not contain the preservative thimerosal or an immune boosting substance known as an adjuvant.

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