HIV Vaccine Regimen Cuts Infections by 31%

BY MICHELE G. SULLIVAN

An investigational HIV vaccine regimen being tested in Thailand has been shown to reduce new infections by 31%.

The placebo-controlled study, consisting of a prime vaccine and three booster shots, was conducted in more than 16,000 Thai citizens who were HIV negative at baseline. After a 3-year follow-up period, infections occurred in 74 of those who received placebo and 51 of those who received the active vaccine—a 31% rate reduction, according to a statement issued by Global Solutions for Infectious Diseases, the company that produces the booster dose.

The reduction was statistically significant, with a *P* value of .04, the statement said. There were no significant safety concerns noted at any of the six safety monitoring points during the trial.

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The RV144 trial is the first HIV vaccine study to show significant disease reduction, Dr. Anthony S. Fauci said in a statement issued by the National Institutes of Health.

"These new findings represent an important step forward in HIV research," said Dr. Fauci, director of the National Institute of Allergy and Infectious Diseases. "For the first time, an investigational HIV vaccine has demonstrated some ability to prevent HIV infection among vaccinated individuals. Additional research is needed to better understand how this vaccine regimen reduced the risk of HIV infection, but certainly this is an encouraging advance for the HIV vaccine field."

The priming vaccine, Sanofi Pasteur's ALVAC-HIV, is a modified canarypox vaccine. The booster dose, AIDSVAX B/E, is a glycoprotein 120 vaccine. The trial began in October 2003. The vaccines are based on the subtype B and E HIV strains, which commonly circulate in Thailand. The subtype B is the one most commonly seen in the United States.

"Separate versions of the vaccine may have to be manufactured and developed for HIV strains that predominate elsewhere in the world, including North America," the GSID statement noted.

The trial comprised noninfected volunteers aged 18-30 years who were considered at risk of contracting HIV. Women comprised 40% of the study population.

Participants who acquired HIV during the trial were given free access to HIV therapy, including highly active antiretroviral therapy, according to the National Institutes of Health statement.

At baseline, participants received HIV protection counseling. They then received the active vaccine or placebo; these were administered again at months 1, 3, and 6. The booster or placebo was also given at months 3 and 6. Subjects were tested for HIV infection every 6 months for 3 years.

The vaccine did not meet its secondary end point, failing to reduce the amount of HIV circulating in the blood of those who became infected during the trial. But because of its success in reducing incident infections, investigation into the prime-boost regimen will continue, the U.S. Military HIV Research Program said in a statement. "Because RV144 is designed to examine plasma viremia soon after infection, trial collaborators have undertaken a second study, RV152, to follow infected individuals over a longer period of time. The results of this study will help to establish the durability of the vaccine effect, if any, on viral load, and assess whether this effect is associated with improved clinical outcome."

The cosponsors of the RV144 trial are the United States Army Medical Research and Material Command, the National Institutes of Allergy and Infectious Diseases, and the Thailand Ministry of Public Health. ■