Evaluation of the safety, reactogenicity and immunogenicity of FluBlok® trivalent recombinant baculovirus-expressed hemagglutinin influenza vaccine administered intramuscularly to healthy adults 50–64 years of age


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ABSTRACT

Background: Alternative methods for influenza vaccine production are needed to ensure adequate supplies.

Methods: Healthy adults 50–64 years were assigned randomly to receive one intramuscular injection of trivalent recombinant hemagglutinin (rHA) or U.S. licensed trivalent inactivated vaccine (TIV) containing H1, H3 and B antigens (Ag) derived from 2007 to 2008 influenza virus strains A/Solomon Islands/03/2006 (H1N1), A/Wisconsin/67/2005 (H3N2), and B/Malaysia/2506/2004. Each rHA dose contained 45_g HA/strain of the 2007–2008 FDA-recommended Ag vs. 15_g/strain for TIV . Antibody (Ab) responses were measured using a hemagglutination-inhibition (HAI) assay at baseline and 28 days post vaccination. Respiratory samples for viral culture were collected from subjects with influenza-like illness (ILI) during the 2007–2008 season in the U.S.

Results: 601 subjects were enrolled. Vaccines were well tolerated. Seroconversion (the percentage of subjects with either (a) a pre-vaccination HAI titer ≤10 and a post-vaccination HAI titer ≥40 or (b) a pre-vaccination titer ≥10 and a minimum four-fold rise in post-vaccination HAI antibody titer) in the TIV and rHA groups, respectively, was obtained in 66% vs. 72% for H1; 44% vs. 61% for H3; and 41% vs. 41% for B. Proportions achieving titers ≥40 were 96% vs. 96% for H1, 75% vs. 85% for H3, and 94% vs. 93% vs. B. Geometric mean titer ratios at day 28 (TIV/rHA) were 0.77 for H1; 0.58 for H3; and 1.05 for B, respectively. ILI frequencies were low and similar in both groups.

Conclusions: Both vaccines were safe and immunogenic. Ab responses vs. H1 and H3 Ags were significantly higher in the rHA group, with similar responses to B. Furthermore, the FluBlok group had a statistically significantly higher seroconversion rate against influenza A/H3N2 compared to the TIV group.

New Technologies to Meet the Challenge of Pandemic Influenza

Albert Price

ABSTRACT

In the early spring of 2009, a new strain of H1N1 influenza emerged and swept across the globe more rapidly than vaccine producers could keep pace. By the time the pandemic abated in February 2010, the US Centers for Disease Control (CDC) estimated that between 8,500 and 17,600 Americans had died from H1N1 infection, with a disproportionate number of deaths occurring among healthy children and young adults. An estimated 15–25% of the nation’s population was exposed to the virus. However, production of vaccine against this aggressive new influenza strain was agonizingly slow. A total of 18 weeks passed between identification of the new virus and the start of the pandemic’s “second wave” — 26 weeks to the peak of that second wave. But the first doses of vaccine did not become available until 26 weeks after strain identification, when spread of the virus was already at its zenith. Vaccine doses sufficient to protect 50% of the US population became available at 38 weeks, and doses to protect 100% of the population were available 48 weeks after strain identification.