ORIGINAL ARTICLE

Efficacy of High-Dose versus Standard-Dose Influenza Vaccine in Older Adults

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ABSTRACT

BACKGROUND

As compared with a standard-dose vaccine, a high-dose, trivalent, inactivated influenza vaccine (IIV3-HD) improves antibody responses to influenza among adults 65 years of age or older. This study evaluated whether IIV3-HD also improves protection against laboratory-confirmed influenza illness.

METHODS

We conducted a phase IIIb–IV, multicenter, randomized, double-blind, active-controlled trial to compare IIV3-HD (60 μg of hemagglutinin per strain) with standard-dose trivalent, inactivated influenza vaccine (IIV3-SD [15 μg of hemagglutinin per strain]) in adults 65 years of age or older. Assessments of relative efficacy, effectiveness, safety (serious adverse events), and immunogenicity (hemagglutination-inhibition [HAI] titers) were performed during the 2011–2012 (year 1) and the 2012–2013 (year 2) northern-hemisphere influenza seasons.

RESULTS

A total of 31,989 participants were enrolled from 126 research centers in the United States and Canada (15,991 were randomly assigned to receive IIV3-HD, and 15,998 to receive IIV3-SD). In the intention-to-treat analysis, 228 participants in the IIV3-HD group (1.4%) and 301 participants in the IIV3-SD group (1.9%) had laboratory-confirmed influenza caused by any viral type or subtype associated with a protocol-defined influenza-like illness (relative efficacy, 24.2%; 95% confidence interval [CI], 9.7 to 36.5). At least one serious adverse event during the safety surveillance period was reported by 1323 (8.3%) of the participants in the IIV3-HD group, as compared with 1442 (9.0%) of the participants in the IIV3-SD group (relative risk, 0.92; 95% CI, 0.85 to 0.99). After vaccination, HAI titers and seroprotection rates (the percentage of participants with HAI titers ≥1:40) were significantly higher in the IIV3-HD group.

CONCLUSIONS

Among persons 65 years of age or older, IIV3-HD induced significantly higher antibody responses and provided better protection against laboratory-confirmed influenza illness than did IIV3-SD. (Funded by Sanofi Pasteur; ClinicalTrials.gov number, NCT01427309.)

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