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Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults.

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ABSTRACT

Background

In previous phase 1-2 clinical trials involving older adults, a subunit vaccine containing varicella-zoster virus glycoprotein E and the $AS01_B$ adjuvant system (called HZ/su) had a clinically acceptable safety profile and elicited a robust immune response.

Methods

We conducted a randomized, placebo-controlled, phase 3 study in 18 countries to evaluate the efficacy and safety of HZ/su in older adults (≥50 years of age), stratified according to age group (50 to 59, 60 to 69, and ≥70 years). Participants received two intramuscular doses of the vaccine or placebo 2 months apart. The primary objective was to assess the efficacy of the vaccine, as compared with placebo, in reducing the risk of herpes zoster in older adults.

Results

A total of 15,411 participants who could be evaluated received either the vaccine (7698 participants) or placebo (7713 participants). During a mean follow-up of 3.2 years, herpes zoster was confirmed in 6 participants in the vaccine group and in 210 participants in the placebo group (incidence rate, 0.3 vs. 9.1 per 1000 person-years) in the modified vaccinated cohort. Overall vaccine efficacy against herpes zoster was 97.2% (95% confidence interval [CI], 93.7 to 99.0; P<0.001). Vaccine efficacy was between 96.6% and 97.9% for all age groups. Solicited reports of injection-site and systemic reactions within 7 days after vaccination were more frequent in the vaccine group. There were solicited or unsolicited reports of grade 3 symptoms in 17.0% of vaccine recipients and 3.2% of placebo recipients. The proportions of participants who had serious adverse events or potential immune-mediated diseases or who died were similar in the two groups.

Conclusions

The HZ/su vaccine significantly reduced the risk of herpes zoster in adults who were 50 years of age or older. Vaccine efficacy in adults who were 70 years of age or older was similar to that in the other two age groups.

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