IMMUNOGENICITY AND SAFETY OF AN ADJUVANTIET HERPES ZOSTER SUBUNIT VACCINE IN OLDER ADULTS PREVIOUSLY VACCINATED WITH A THREE-DOSAGE, LIVE-ATTENUATED HERPES ZOSTER VACCINE: A PHASE III, GROUP-MATCHED, CLINICAL TRIAL

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ABSTRACT

Study participants

A total of 315 adults (median age 72 years; range 65–86 years) who were previously vaccinated with 2 or 3 doses of live-attenuated herpes zoster vaccine (HZE) were matched with 315 participants vaccinated with 2 doses ≥5 years earlier (HZE-PreVac) according to pre-specified matching characteristics (Table 1). The demographic characteristics were comparable between study groups (Table 1).

Conclusions and discussion

The immunogenicity and safety results at 1 month post-dose 2 were consistent with previous studies. The frequency of reported unsolicited adverse events was low. No new safety signals emerged, and no post-licensure surveillance was required for the HZ/su vaccine.

Disclosures

GlaxoSmithKline (GSK) funded this study and is the developer of the adjuvanted and post-licensure vaccine. T.C. Heineman is an employee of GlaxoSmithKline and has received honoraria from GSK and the Kaiser Permanente Vaccine Study Center, Oakland, California, US. J. Peterson is an employee of Pfizer and has received honoraria from Pfizer. M. Campara, M. Dohle, N. Kiely, H. J. Li and L. Oostvogels declare no conflicts of interest.

REFERENCES


METHODS

In this phase II, group-matched, open-label, prospective, multicenter trial (NCT02554514) conducted in the United States, a random sample of 315 adults (aged ≥65 years) who received ≥2 doses of live-attenuated herpes zoster vaccine (HZE) were matched with 315 adults who received ≥1 dose of HZE at least 5 years earlier (HZE-PreVac) (Figure 1).

Figure 1. Study design

Figure 2. 1 month post-dose 1

Figure 3. 30 days after dose 1

Figure 4. Local General Adverse Events

Figure 5. Adverse Events

Figure 6. Adverse Events

RESULTS

The incidence of all grade and grade 3 solicited local and general AEs was similar between study groups (Figure 5). The solicited AEs were transient and their median duration was 3 days for local AEs and 2 days for general AEs.

The primary immunogenicity objective was met (pre-defined criterion: upper limit of the 95% confidence interval (CI) for the adjusted geometric mean ratio (GMR) of ≥0.70). The geometric mean ratios (GMRs) with 95% CI were as follows:

- For HZ/su: 204; 95% CI = 1.38–1.67
- For HZ-PreVac: 204; 95% CI = 1.38–1.67

No new safety signals emerged, and post-licensure surveillance was not required for the HZ/su vaccine.

The incidence of solicited AEs was similar between groups up to the end of study. For HZ/su, no serious solicited AEs occurred, and no solicited AEs were reported after M3.

Figure 6. Incidence of local and general solicited AEs

Figure 7. Incidence of all solicited AEs

Table 1. Demographic characteristics

Table 2. Incidence of unsolicited AEs

Table 3. Incidence of unsolicited AEs

Table 4. Incidence of unsolicited AEs

Table 5. Incidence of unsolicited AEs

Table 6. Incidence of unsolicited AEs

Table 7. Incidence of unsolicited AEs

CONCLUSIONS AND DISCUSSION

Vaccination with 2 doses of HZE, 3 months apart, elicited strong humoral immune responses in adults ≥65 years of age who had previously been vaccinated with the live-attenuated herpes zoster vaccine (HZE) ≥5 years earlier. The immune response to HZE/su in previously HZE-vaccinated adults ≥65 years was non-inferior to that of HZE-PreVac recipients. Therefore, we assessed the immunogenicity and safety of HZ/su in adults ≥65 years of age who had previously been vaccinated with ≥2 doses of HZE ≥5 years earlier, compared to HZE-naive individuals (HZE-NonVac group).

The authors would like to thank all study participants and all staff members at the study sites for their contributions to the study.

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