A varicella-zoster virus vaccine reduced the burden of illness of herpes zoster in older adults


Clinical impact ratings GP/FP/Primary care ★★★★★☆ IM/Ambulatory care ★★★★★☆ Infectious disease ★★★★★☆

In persons ≥60 years of age, does a live attenuated varicella-zoster virus (VZV) vaccine decrease the burden of illness caused by herpes zoster and the incidence of postherpetic neuralgia?

METHODS

- **Design:** randomised placebo controlled trial (Shingles Prevention Study).
- **Allocation:** (concealed)†.
- **Blinding:** blinded (clinicians, participants, [data collectors, outcome assessors, data analysts, and data safety and monitoring committee]) †.
- **Follow-up period:** mean 3.13 years.
- **Setting:** 22 sites in the US.
- **Participants:** 38 546 persons ≥60 years of age (median age 69 y, 59% men) who had a history of varicella or had lived in the US ≥30 years. Immunocompromised persons were excluded.
- **Intervention:** 1 subcutaneous injection of 0.5 ml of Oka/Merck VZV vaccine (n = 19 270), or placebo (n = 19 276). The vaccine had median estimated potency of 24 600 plaque forming units.
- **Outcomes:** vaccine efficacy with respect to the severity of illness caused by herpes zoster, defined as the relative reduction in burden of illness score (VEBOI) based on the severity of herpes zoster pain and its duration, comparing the vaccine and placebo groups. For the vaccine to be considered a success, the VEBOI point estimate had to be ≥47% with the lower limit of the 95% CI ≥25%. The secondary outcome was vaccine efficacy with respect to the incidence of post-herpetic neuralgia (VEPHN) defined as pain rated as ≥3 (scale ranged from 0–10 [pain as bad as you can imagine]). The vaccine was considered a success if the VEPHN point estimate was ≥62% with a 95% CI lower limit >25%.
- **Patient follow up:** 95% (modified intention to treat analysis).

†See glossary.  †Information provided by author.

MAIN RESULTS

315 participants in the vaccine group and 642 in the placebo group developed herpes zoster. The incidence of herpes zoster was lower in the vaccine group (table). The herpes zoster burden of illness score was lower in participants who received the vaccine than in those who received placebo (score 2.21 v 5.68, 61% reduction, p<0.001). The results were not affected when stratified by sex or age. 27 participants in the vaccine group and 80 in the placebo group developed post-herpetic neuralgia (table); the results were not affected by sex or age.

CONCLUSIONS

In persons ≥60 years of age, a live attenuated varicella zoster virus vaccine decreased the burden of illness caused by herpes zoster and the incidence of post-herpetic neuralgia. The vaccine reduced the incidence of herpes zoster.

Abstract and commentary also appear in ACP Journal Club.

| Varicella-zoster vaccine (VZV) v placebo to prevent herpes zoster at mean 3.13 years* |
|-----------------------------------------|-----------------|-----------------|-----------------|
| **Outcomes**                            | **Incidence per 1000 person-years** |
|                                         | VZV vaccine | Placebo | NNT (95% CI) | Vaccine efficacy (CI) |
| Incidence of herpes zoster              | 5.42        | 11.12   | 59 (50 to 72) | 51% (44 to 58) |
| Incidence of post-herpetic neuralgia    | 0.46        | 1.38    | 364 (259 to 577) | 67% (48 to 79) |

*Abbreviations defined in glossary; NNT and CI calculated from number of confirmed cases of herpes zoster and post-herpetic neuralgia in article.
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