

NON-INTERVENTIONAL STUDY REPORT (ABSTRACT)

Title	Non-interventional (observational) post-licensure study to assess the effectiveness and safety of recombinant zoster vaccine in adults aged ≥ 18 years with psoriasis or psoriatic arthritis
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Name and affiliation of main author	PPD Kaiser Permanente Southern California
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Marketing authorisation holder(s)	GlaxoSmithKline Biologicals S.A.
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Rationale and background

Studies have shown higher incidence of herpes zoster (HZ) in individuals with altered immune function, compared to the general population. Real-world data on the effectiveness and safety of recombinant zoster vaccine (RZV) in such at-risk populations are needed to help inform patient and physician decision-making regarding vaccination against HZ.

Research questions and objectives

Primary and secondary VE objectives estimated the VE of 2 doses of RZV in preventing HZ in adults ≥ 18 years of age with PsO or PsA, separately and with either condition. One-dose VE was estimated, and the baseline characteristics of the RZV-vaccinated and unvaccinated cohorts were described as secondary objectives. The primary and secondary safety objectives assessed the rate of flares within 30 days following RZV vaccination as compared to the rate in self-controlled comparison windows. CCI

CCI

Study design

For VE objectives, an observational matched cohort design was used in which RZV vaccinated individuals were compared to matched RZV unvaccinated individuals. For safety objectives, a self-controlled case series design was used to evaluate the rate of flare. Accrual occurred from 01 April 2018 up to 31 December 2023 with follow-up through 31 December 2024 for HZ outcomes, and up to 30 June 2025 for CCI

Setting

Kaiser Permanente Southern California includes 4.6 million members. The demographic makeup of the KPSC membership closely mirrors the Southern California population.

Subjects and study size, including dropouts

The primary VE analyses included 10,391 PsO (2,616 vaccinated and 7,765 unvaccinated) and 2,163 PsA (548 vaccinated and 1,615 unvaccinated) individuals. The PsO and PsA safety cohorts included 3,086 and 1,073 vaccinated individuals, respectively.

Variables and data sources

Individuals with at least 2 previous encounters with assigned ICD-10 codes for PsO or PsA were identified from electronic health records (EHR). The primary exposure for VE analysis was 2 doses of RZV. The primary outcome for VE analysis was HZ, identified by ICD-10 code and antiviral prescription. The primary outcome for safety analysis was clinically relevant flares identified from EHR by trained staff.

Results

The adjusted VE of 2 doses of RZV against HZ in adults (≥ 18 years) was 60.7 (95% confidence interval [CI]: 40.5%, 74.0%) and 80.5% (95% CI: 34.3%, 94.2%) for PsO and PsA patients, respectively. The rate of flares was comparable across the risk and comparison windows for recipients of RZV with PsO (incidence rate ratio [IRR]= 0.94, 95% CI: 0.58, 1.52) and PsA (IRR= 1.21, 95% CI: 0.69, 2.13).

Discussion

Previous work evaluating the effectiveness and safety of RZV has largely focused on immunocompetent adults and older populations. This study also addressed the younger, immunocompromised population by expanding inclusion criteria to include ≥ 18 -year-olds with PsO and PsA using real-world data from a large integrated health care delivery network.

Conclusion

For adults with PsO and PsA, 2 doses of RZV conferred protection against HZ with no elevated rate of flares observed in the 30 days following vaccination. Our findings support the recommendation to vaccinate adults with PsO and PsA with 2 doses of RZV.