

# Non-interventional (observational) post-licensure study to assess the effectiveness and safety of recombinant zoster vaccine in adults aged $\geq 18$ years with psoriasis or psoriatic arthritis (EPI-ZOSTER-045 VE US 216976)

**First published:** 20/10/2023

**Last updated:** 18/03/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS107230

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### Study ID

108334

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### DARWIN EU® study

No

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### Study countries

## Study description

This is an observational retrospective study using existing data sources.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### GlaxoSmithKline (GSK)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

#### Kaiser Permanente Southern California (KPSC)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Call Center EU GSK Clinical Trials RD.CTT-  
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Study contact

[RD.CTT-globalmailbox@gsk.com](mailto:RD.CTT-globalmailbox@gsk.com)

**Primary lead investigator**

Call Center EU GSK Clinical Trials

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 06/12/2022

Actual: 06/12/2022

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**Study start date**

Planned: 09/11/2023

Actual: 09/11/2023

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**Date of final study report**

Planned: 03/07/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

# Study protocol

[Protocol Anonymized\\_216976.pdf](#) (1.65 MB)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

For the Vaccine Effectiveness (VE) objectives, an observational matched cohort design will be used. For safety objectives, a self-controlled case series (SCCS) analysis will be conducted

**Main study objective:**

- To estimate the vaccine effectiveness of 2 doses of recombinant zoster vaccine (RZV) in preventing Herpes Zoster (HZ) in Southern California adults  $\geq 18$  years of age with psoriasis (PsO).
- To assess the rate of flares within 30 days following RZV vaccination as compared to the rate in self-controlled comparison periods, in Southern California adults  $\geq 18$  years of age with PsO.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

SHINGRIX

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**Study drug International non-proprietary name (INN) or common name**

HERPES ZOSTER VACCINE (RECOMBINANT, ADJUVANTED)

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BK03) zoster, purified antigen

zoster, purified antigen

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**Medical condition to be studied**

Psoriasis

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**Additional medical condition(s)**

Psoriatic arthritis

## Population studied

**Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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**Estimated number of subjects**

12802

## Study design details

**Outcomes**

Vaccine effectiveness in preventing HZ in Southern California participants with PsO.

Rate of flares in Southern California participants with PsO. Vaccine effectiveness

in preventing HZ in South California participants with:

- PsO or PsA (2 doses of RZV),
- PsA (2 doses of RZV),
- PsO (1 dose of RZV),
- PsA (1 dose of RZV).

Baseline characteristics in Southern California participants with:

- PsO (2 doses of RZV),
- PsA (2 doses of RZV).

Rate of flares in Southern California participants with:

- PsO or PsA,
- PsA.

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### **Data analysis plan**

Baseline demographic and clinical characteristics of individuals with PsO or PsA, who meet the inclusion criteria will be described. Categorical variables will be presented as absolute numbers and percentages for each cohort. Continuous variables such as age in years will be presented as the mean with standard deviation and/or median with interquartile ranges. For vaccine effectiveness objectives, incidence rates of HZ will be assessed for the PsO and PsA cohort. Unadjusted and adjusted vaccine effectiveness will be calculated using hazard ratios, which will be estimated by Cox proportional hazards regression models with and without adjustment for potential confounders. For safety objectives, rates of PsO or PsA flare for risk periods and comparison periods will be calculated. Incidence rate ratio comparing the rate of flares in the risk and comparison periods will be estimated using conditional Poisson regression.

## Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data source(s), other

Kaiser Permanente Health Connect, United States

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

No