

219111- A retrospective matched cohort database study in the United States to evaluate the effectiveness of recombinant zoster vaccine (RZV) in patients with autoimmune diseases (AIDs) (EPI-ZOSTER-097 VE US DB)

**First published:** 13/10/2022

**Last updated:** 13/12/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS49294

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### Study ID

49979

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### DARWIN EU® study

No

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### Study countries

### Study description

A retrospective matched cohort database study to provide early real-world evidence of the effectiveness of RZV in patients aged 50 years of age and older with autoimmune diseases in the United States.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### GlaxoSmithKline (GSK)

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

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

Institution

## Contact details

### Study institution contact

Call Center EU Clinical Trials

Vx.publicdisclosureglobal@gsk.com

Study contact

[Vx.publicdisclosureglobal@gsk.com](mailto:Vx.publicdisclosureglobal@gsk.com)

## Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 22/08/2022

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### Study start date

Planned: 14/10/2022

Actual: 14/10/2022

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### Date of final study report

Planned: 29/10/2024

Actual: 29/10/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline Biologicals SA

## Study protocol

[Redacted Protocol Anonymized 29 Sep 2022.pdf](#) (1.26 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)

**Main study objective:**

To estimate the VE of 2 doses of RZV in preventing HZ in participants with one of the following conditions: Systemic Lupus Erythematosus (SLE), Multiple Sclerosis (MS), Rheumatoid Arthritis (RA), Inflammatory Bowel Disease (IBD), Psoriasis (PsO) or Psoriatic Arthritis (PsA).

## Study Design

## Non-interventional study design

Cohort

Other

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## Non-interventional study design, other

Retrospective matched cohort database study

# 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

Herpes zoster

# Population studied

## Age groups

- Adults (46 to < 65 years)
- Elderly ( $\geq$  65 years)
  - Adults (65 to < 75 years)

- Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Special population of interest**

Immunocompromised

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### **Estimated number of subjects**

42755

## Study design details

### **Outcomes**

Number of HZ cases after 2 RZV doses in participants with SLE, MS, RA, IBD, PsO and PsA.

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### **Data analysis plan**

The number and characteristics of participants in each cohort will be described and compared. Categorical variables such as gender will be presented as absolute numbers and percentages with p-values for the Pearson  $\chi^2$  test or Fisher's exact test, as appropriate. Continuous variables such as age in years will be presented as the mean with standard deviation and/or median with interquartile ranges, with p-values for the two-sample t-test or Wilcoxon rank-sum test, as appropriate. Absolute standardized differences will be calculated to assess the balance of covariates with a cut-off value of 0.20. Overall incidence rates of HZ for the 2-dose (>28 days apart) and the 1-dose RZV vaccinated cohort and the matched unvaccinated cohort will be calculated by dividing the number of HZ cases by the total number of person-years.

## Documents

## Study report

[Clinical Study Report Anonymised.pdf](#) (4.02 MB)

## 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

Optum Database (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