209696 - A targeted safety study, EPI-ZOSTER-032 VS US DB, to evaluate the safety of Shingrix in adults ≥ 65 years of age in the United States.

First published: 11/09/2020

Last updated: 29/07/2026

Study Finalised

Administrative details

EU PAS number

EUPAS37133

Study ID

48959

DARWIN EU® study

No

Study countries

United States

Study description

Targeted safety study to assess the real-world safety of Shingrix vaccine in the US using the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Warehouse (CCW) database with a focus on specific health outcomes of interest in adults aged 65 and older.

Study status

Finalised

Contact details

Study institution contact

Call Center EU Clinical Trials

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Study contact

Vx.publicdisclosureglobal@gsk.com

Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/08/2020

Study start date

Planned: 11/09/2020

Actual: 11/09/2020

Date of final study report

Planned: 02/07/2026

Actual: 02/07/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

Redacted EPI-ZOSTER-032 Protocol Amendment 3 Anonymized 16 Aug 2022.pdf (914.29 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Self-Controlled Risk Interval (SCRI) study design. A cohort design was implemented to assess the risk of new onset PMR, GCA and ION within 183 days following RZV vaccination compared to an RZV-unvaccinated cohort who had a preventive care visit.

Main study objective:

To assess whether Shingrix, or RZV, is associated with an increased risk of new-onset Guillain-Barré Syndrome (GBS), Gout, Polymyalgia Rheumatica (PMR), Giant Cell Arteritis (GCA), Ischemic Optic Neuropathy (ION) or Supraventricular Tachycardia (SVT) within specified time periods after vaccination in people ≥ 65 years of age beginning January 2018 in CMS Medicare.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Targeted safety study (TSS) and a post-authorization safety study (PASS)

Study drug and medical condition

Medicinal product name

SHINGRIX

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

HERPES ZOSTER VACCINE (RECOMBINANT, ADJUVANTED)

Anatomical Therapeutic Chemical (ATC) code

(J07BK03) zoster, purified antigen

zoster, purified antigen

Medical condition to be studied

Herpes zoster

Population studied

Short description of the study population

The study population included patients aged 65 years or older who had received at least one dose of Shingrix, recombinant zoster vaccine (RZV) for the treatment of herpes zoster identified from CMS chronic conditions warehouse Medicare database from January 2017 to December 2021.

Inclusion criteria:

US Medicare beneficiaries who meet the following criteria will be included in the study:
1. Age 65 and older at the date of the RZV vaccination or preventive care visit for the RZV unvaccinated comparator
2. Enrolled in Medicare due to age or ESRD as the original and current qualifying reason
3. Continuously enrolled in Medicare Parts A, B, and D fee-for-service for at least 365 days preceding the date of RZV vaccination or preventive care visit for the RZV unvaccinated comparator. Continuous enrollment is determined by Medicare enrollment in the month of the RZV vaccination or preventative care visit and enrollment in at least 11 of the 12 preceding months.

Exclusion criteria:
Beneficiaries who satisfy the following criteria will be excluded:
1. Continuously enrolled only in Medicare Part C in the baseline period, OR
2. Enrolled in Medicare due to disability as the original qualifying reason for enrollment.

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

723.000

Study design details

Setting

The source population includes US adults age 65 and older who are enrolled in Medicare any time from 2017 through 2021.

Comparators

RZV unvaccinated comparators

Outcomes

The risk of new onset GBS (within 42 days) and Gout (within 30 days) following RZV vaccination using a Self-controlled Risk Interval (SCRI) design and the risk of new onset PMR (within 183 days) and GCA (within 183 days) following RZV vaccination using a cohort design. The risk of new onset SVT within 30 days following RZV vaccination using a SCRI design and the risk of new onset ION within 183 days following RZV vaccination using a cohort design.

Data analysis plan

The analysis plan will include descriptive measures to characterize exposed and unexposed individuals, conditional Poisson regression models for the SCRI, and Cox proportional hazards regression models for the cohort design outcomes For each outcome there is a primary analysis, secondary analysis and sensitivity analysis All the statistical analyses will be done in Statistical Analysis System 9.4. All the statistical tests will be two-sided at alpha level of 0.05. All 95% confidence intervals will be estimated as the point estimate +/- 1.96*standard error.

Summary results

In the primary analysis of outcomes evaluated using the SCRI design, that did not distinguish between doses, the RR of new onset GBS was 3.15 (95% CI: 1.82, 5.68) and the AR was 6.59 per 1 000 000 vaccine doses (95% CI: 4.35, 7.96), the RR of new onset gout was 1.00 (95% CI: 0.90, 1.12, and the RR of new onset SVT was 0.94 (95% CI: 0.89, 0.99). The primary analysis of outcomes

evaluated using a cohort design, that evaluated the risk after Dose 1 and Dose 2 separately, did not show a statistically significant risk of PMR from Day 1 to 120 following Dose 1 (HR=1.00; 95% CI: 0.92, 1.09). After Day 120, there was a statistically significant increased risk of PMR following Dose 1: HR=2.05 (95% CI: 1.71, 2.46). The results did not reveal a statistically significant increased risk of GCA from Day 1 to 150 following RZV Dose 1 (HR=1.10; 95% CI: 0.94, 1.28) or after Day 150 (HR=1.34; 95% CI: 0.89, 2.01). Results from the Dose 2 primary analysis did not show an increased risk of GCA. The primary analysis using an IPTW stabilized weighted Cox proportional hazards regression analysis did not reveal a statistically significant risk of ION following RZV Dose 1 (HR=0.97, 95% CI: 0.90, 1.05) but showed a statistically significant lower risk of ION following RZV Dose 2 (HR=0.85, 95% CI: 0.78, 0.93) relative to the RZV-unvaccinated comparators.

Documents

Abstract of study report

Abstract-Anonymised 10 Jul 2026.pdf (131.5 KB)

Study report

Clinical Study Report Body-Anonymised 10 Jul 2026.pdf (13.94 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

CMS Medicare database US United States

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No