209452 - A targeted safety study, EPI-ZOSTER-030 VS US DB, to evaluate the safety of Shingrix in adults ≥ 50 years of age in the United States

First published: 11/09/2020

Last updated: 14/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS37156

Study ID

50411

DARWIN EU® study

No

Study countries

United States

Study description

Targeted safety study to assess the real-world safety of Recombinant zoster vaccine (RZV) in the US using a large distributed data network with a focus on specific health outcomes of interest in adults aged 50 and older.

Study status

Ongoing

Research institutions and networks

Institutions

Harvard Pilgrim Health Care Institute

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

Harvard Pilgrim Health Care, Aetna, CVS Health Company, Carelon Research, Humana, Optum

Contact details

Study institution contact

Call Center EU Clinical Trials
Vx.publicdisclosureglobal@gsk.com

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: 27/08/2020

Study start date
Planned: 14/09/2020

Actual: 14/09/2020

Date of final study report
Planned: 05/08/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

Protocol_Amendment_2_Anonymized_209452.pdf (1.11 MB)

Protocol_Amendment_5-Anonymised.pdf (1.84 MB)

Protocol Amendment 4 Anonymised 16 May 2025.pdf (2.96 MB)

Protocol Amendment 3 Anonymised 20 May 2025.pdf (3.5 MB)

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)

Main study objective:

To assess whether there is 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 RZV vaccination in people ≥ 50 years of age enrolled starting in January 2018 at any of the participating U.S. Research Partners.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Self-controlled risk interval design (a version of the self-controlled case series and the case-crossover designs)

Study drug and medical condition

Medicinal product name

SHINGRIX

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

RECOMBINANT VARICELLA ZOSTER VIRUS GLYCOPROTEIN E

Anatomical Therapeutic Chemical (ATC) code

(J07BK) Varicella zoster vaccines

Varicella zoster vaccines

Medical condition to be studied

Herpes zoster

Population studied

Short description of the study population

The study population will be commercially insured people in the US who are ≥50 years of age at the time of their
qualifying visit date (i.e., RZV vaccination date for RZV recipients or preventive care visit date for cohort study comparators) during the study period, from 01 January 2018 on. Administrative-services-only enrollees will be excluded, as their medical records may not be available for review; however, ASO enrollees may be considered for inclusion on an as-needed basis, if allowable and medical records are available.

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

723000

Study design details

Comparators

For GBS, the risk during Days 1-42 after RZV vaccination will be compared with the risk in a post-vaccination
control interval starting on Day 43 after Dose 1. For gout and SVT, the risk during Days 1-30 after RZV vaccination will be compared with the risk in a post-vaccination control interval starting on Day 31 after Dose 1

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 includes 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 Sentinel analytic tools will be used for the distributed analyses, modifications to the tools may be needed to meet study objectives. For each outcome there is a primary analysis, secondary analysis and sensitivity analysis. All the statistical calculations will be done in SAS 9.2 or higher.

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)

Network of Sentinel General Practitioners

Data source(s), other

Sentinel Distributed Database (SDD) 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