Effectiveness of Adjuvanted Recombinant Zoster Vaccine (RZV) Against Postherpetic Neuralgia (PHN) and Against Cardiovascular Disease (CVD) Events After Herpes Zoster (HZ) in United States Adults in Medicare Fee-for-Service (FFS) + Inovalon's MORE2 Registry (307298 - EPI-ZOSTER-116 VE DB US)

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Study Planned

Administrative details

EU PAS number

EUPAS1000001125

Study ID

1000001125

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Research institutions and networks

Institutions

GlaxoSmithKline Biologicals SA

Inovalon

Contact details

Study institution contact

Call Center EU GSK Clinical Trials RD.CTT-globalmailbox@gsk.com

Study contact

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: 28/01/2026

Actual: 28/01/2026

Study start date
Planned: 26/10/2026

Date of final study report
Planned: 09/06/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

Protocol Amendment 1 Anonymised 17 Sep 2026.pdf (1.89 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a retrospective, matched cohort study.

Main study objective:

• To estimate the VE of 2 doses of RZV (2-6 months apart) in preventing PHN in adults aged ≥50 years, overall and by follow-up year since vaccination.

• To estimate the VE of 2 doses of RZV (2-6 months apart) in preventing 3-point MACE (composite of hospitalized AMI, hospitalized stroke, or cardiovascular death) occurring within 3 months after HZ diagnosis in adults aged ≥50 years, overall.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SHINGRIX

Medicinal product name, other

Recombinant Zoster Vaccine

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

Additional medical condition(s)

Postherpetic Neuralgia, Cardiovascular Disease

Population studied

Short description of the study population

Eligible adults in 100% Medicare FFS and in MORE2 Registry between 01 October 2015 and 31 December 2024.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest

Immunocompromised

Study design details

Comparators

RZV unvaccinated comparator: individuals will be selected for the ‘no RZV’ unvaccinated comparator group from individuals with a preventive care visit who have no record of RZV vaccination prior to or on the preventive care visit date.

Outcomes

Vaccine effectiveness of RZV against:

• PHN

• HZ-associated hospitalization

• Other HZ complications (HZO)

• 3-point MACE within 3 months after HZ - composite of hospitalized AMI, hospitalized stroke, or cardiovascular death

• 3-point MACE within 3 months after HZ - components: hospitalized AMI within 3 months after HZ, hospitalized stroke within 3 months after HZ, cardiovascular death within 3 months after HZ

• 3-point MACE within [timeframe] after HZ – composite and components

Adjusted hazard ratio of:

• All-cause 3-point MACE – composite

• All-cause hospitalized AMI

• All-cause hospitalized stroke (ischemic or hemorrhagic)

• All-cause cardiovascular death

Data analysis plan

A series of matched, multivariable, and weighted analyses will be conducted to address the research objectives focused on assessing the VE (including incidence rate and hazard ratio) of new diagnosis of PHN and 3-point MACE after HZ as well as other HZ complications.

Summary results

The summary of results will be available within 12 months since end of study date.

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 data source

Data source(s), other

This study will leverage 100% Medicare FFS data and the MORE2 Registry database at Inovalon.

Veritas Data Research mortality data.

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Mortality data

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes