Safety and effectiveness of RZV in adults ≥18 years of age with Systemic lupus erythematosus (SLE) or Multiple sclerosis (MS) (EPI-ZOSTER-041 VS US DB 215104)

First published: 18/10/2023

Last updated: 05/09/2025

Study | Ongoing

Administrative details

EU PAS number

EUPAS107073

Study ID

108331

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is an observational study based on data extracted from database(s), which evaluates the safety and vaccine effectiveness of Shingrix, or recombinant zoster vaccine (RZV), in adults with pre-existing systemic lupus erythematosus (SLE) or multiple sclerosis (MS).

Study status

Ongoing

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Harvard Pilgrim Health Care Institute

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Call Center EU GSK Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/08/2021

Actual: 24/08/2021

Study start date

Planned: 20/10/2023

Actual: 20/10/2023

Date of final study report

Planned: 15/01/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

Protocol Amendment_Anonymized_215104.pdf (2.47 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:

Disease /health condition

Study type:

Non-interventional study

Main study objective:

• To assess the risk of severe flare within 90 days following any RZV dose in adults with pre-existing SLE.

• To assess the risk of any relapse within 90 days following any RZV dose in

adults with pre-existing MS.

• To estimate the VE of 2 doses of RZV in preventing HZ in adults with pre-existing SLE.

• To estimate the VE of 2 doses of RZV in preventing HZ in adults with pre-existing MS.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

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

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)

Estimated number of subjects

48693

Study design details

Outcomes

Safety: Risk of severe systemic lupus erythematosus (SLE) flare or risk of any multiple sclerosis (MS) relapse.

Effectiveness: Vaccine effectiveness in prevention of herpes zoster (HZ).

Effectiveness: Incidence of post-herpetic neuralgia (PHN).

Data analysis plan

The analysis plan will include descriptive measures to characterize vaccinated and unvaccinated individuals. Cox proportional hazards regression models will be used to compare outcomes in vaccinated and unvaccinated patients using propensity scores to balance potential confounders.

To evaluate safety outcomes after any RZV dose, separate cohorts will be created for RZV Dose 1 and Dose 2, each with matched unvaccinated comparators.

Severe SLE flares and any MS relapses will be assessed separately in each cohort (Dose 1 and Dose 2) first descriptively, and using time-to-event analysis with Cox proportional hazard models, assessing for violations of the proportional hazards assumptions.

A retrospective cohort design with Cox proportional hazards modelling will be used to assess the risks of HZ and incidence of PHN after RZV vaccination. In

the primary analysis, patients receiving the RZV Dose 2 at least 28 days after RZV Dose 1 will be compared to patients with no prior RZV vaccination.

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

US FDA Sentinel System Centers for Medicare and Medicaid Services (CMS) – Medicare 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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No