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: 02/07/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/108331

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 institution and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024
Last updated 01/02/2024

Institution

Harvard Pilgrim Health Care Institute

First published: 01/02/2024
Last updated 01/02/2024

Institution

Contact details

Study institution contact

Call Center EU GSK Clinical Trials

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:
24/08/2021
Actual:
24/08/2021

Study start date

Planned:
19/10/2023
Actual:
20/10/2023

Date of final study report

Planned:
24/03/2027

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 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

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

Data sources

Data source(s), other
US FDA Sentinel System Centers for Medicare and Medicaid Services (CMS) – Medicare United States

Data sources (types)
Administrative data (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