209570 - Long-Term Effectiveness Study of Shingrix in Adults ≥ 50 Years of Age in the US (EPI-ZOSTER-031 VE US)

First published: 16/12/2020

Last updated: 18/03/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46860

EU PAS number

EUPAS38633

Study ID

46860

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study will evaluate the long-term Vaccine Effectiveness (VE) among individuals ≥ 50 Years who received RZV compared to individuals who did not receive RZV, followed for up to 10 years following the last dose of RZV.

Study status

Ongoing

Research institutions and networks

Institutions

Kaiser Permanente Southern California (KPSC)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Call Center EU Clinical Trials

Study contact

GSKClinicalSupportHD@gsk.com

Primary lead investigator

Hung Fu Tseng

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 30/05/2020

Study start date
Actual: 18/12/2020

Date of final study report
Planned: 14/10/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-209570-protocol-redact-01.pdf(905.32 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To assess VE among individuals at KPSC who received RZV (“vaccinated”) compared to individuals who did not receive RZV (“RZV unvaccinated”) with 10 years of follow-up.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

SHINGRIX

Medical condition to be studied

Herpes zoster

Population studied

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

800000

Study design details

Outcomes

The VE of 2 doses of RZV in preventing HZ and the VE of 2 doses of RZV in preventing PHN in adults aged ≥ 50 years, when the second dose is received 4 weeks to 6 months after the first dose, during a 10 year follow up period post second dose of vaccination. RZV VE-2 doses preventing HZ&PHN stratified by age, sex& race/ethnicity, RZV VE-2 doses preventing HZ by prevalent comorbidities at baseline &ZVL history, HZ incidence in vaccinated(2 doses) & unvaccinated adults, by HZ history, RZV VE-2 doses preventing HZO, hospitalized AMI &hospitalized stroke, doses given 4 weeks-6 months post 2nd

dose. RZV VE-1 dose preventing HZ&PHN in adults post 1st dose

Data analysis plan

The number and characteristics of individuals will be described and compared. Categorical variables will be presented as absolute numbers and percentages with p-values for the χ2 test. Continuous variables such as age in years will be presented as the mean with standard deviation and/or median with interquartile ranges, with p-values for the two-sample t-test or Wilcoxon rank-sum test, as appropriate. All the statistical calculations will be performed using SAS software package (version 9.4). Adjusted hazard ratios (HRs) and 95% confidence intervals (CIs) comparing HZ incidence rates in the 2-dose (4 weeks to 6 months) RZV cohort and the matched unvaccinated cohort will be estimated by Cox proportional hazards regression models adjusting for potential confounders.

Data management

Data sources

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