219111- A retrospective matched cohort database study in the United States to evaluate the effectiveness of recombinant zoster vaccine (RZV) in patients with autoimmune diseases (AIDs) (EPI-ZOSTER-097 VE US DB)

First published: 13/10/2022

Last updated: 13/12/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49979

EU PAS number

EUPAS49294

Study ID

49979

DARWIN EU® study

No

Study countries

☐ United States

Study description

A retrospective matched cohort database study to provide early real-world evidence of the effectiveness of RZV in patients aged 50 years of age and older with autoimmune diseases in the United States.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Call Center EU Clinical Trials

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

Planned: 22/08/2022

Study start date

Planned: 14/10/2022

Actual: 14/10/2022

Date of final study report

Planned: 29/10/2024

Actual: 29/10/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline Biologicals SA

Study protocol

Redacted Protocol Anonymized 29 Sep 2022.pdf(1.26 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)

Main study objective:

To estimate the VE of 2 doses of RZV in preventing HZ in participants with one of the following conditions: Systemic Lupus Erythematosus (SLE), Multiple

Sclerosis (MS), Rheumatoid Arthritis (RA), Inflammatory Bowel Disease (IBD), Psoriasis (PsO) or Psoriatic Arthritis (PsA).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective matched cohort database study

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

Medical condition to be studied

Herpes zoster

Population studied

Age groups

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

Estimated number of subjects

42755

Study design details

Outcomes

Number of HZ cases after 2 RZV doses in participants with SLE, MS, RA, IBD, PsO and PsA.

Data analysis plan

The number and characteristics of participants in each cohort will be described and compared. Categorical variables such as gender will be presented as absolute numbers and percentages with p-values for the Pearson $\chi 2$ test or Fisher's exact test, as appropriate. 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. Absolute standardized differences will be calculated to assess the balance of covariates with a cut-off value of 0.20. Overall incidence rates of HZ for the 2-dose (>28 days apart) and the 1-dose RZV vaccinated cohort and the matched unvaccinated cohort will be calculated by dividing the

number of HZ cases by the total number of person-years.

Documents

Study report

Clinical Study Report Anonymised.pdf(4.02 MB)

Data management

Data sources

Data source(s), other

Optum Database (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