213825-Non-interventional (observational) post-licensure study to assess the vaccine effectiveness and safety of recombinant zoster vaccine (RZV) in the rheumatoid arthritis (RA) and inflammatory bowel disease (IBD) patient populations in adults 18 years of age and older (EPI-ZOSTER-044 VE US)

First published: 21/07/2022

Last updated: 10/02/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48446

EU PAS number

EUPAS48157

Study ID

48446

DARWIN EU® study

No

Study countries

☐ United States

Study description

An observational retrospective study using existing data sources.

Study status

Ongoing

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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

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Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/03/2022

Study start date

Planned: 21/07/2022

Actual: 21/07/2022

Date of final study report

Planned: 26/11/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline Biologicals SA

Study protocol

gsk-213825-protocol-redact.pdf(702.08 KB)

Protocol Amendment 1 Anonymized 16 Jul 2024.pdf(1.73 MB)

Regulatory

Was the study required by a regulatory body?

No

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)

Safety study (incl. comparative)

Main study objective:

To estimate the VE of 2 doses of RZV, given 4 weeks to 6 months apart, in preventing HZ in adults ≥18 years of age with RA and IBD.

To assess the risk of RA and IBD flares within 30 days following any RZV vaccination as compared to the risk in self-controlled comparison periods, in adults ≥18 years of age with RA and IBD respectively.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Name of medicine

SHINGRIX

Medical condition to be studied

Herpes zoster

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)

Special population of interest

Immunocompromised

Estimated number of subjects

21500

Study design details

Outcomes

Number of incident HZ cases in participants with RA and IBD

Incidence rate of HZ in participants with RA and IBD

Number of incident RA and IBD flare cases

Number of incident HZ cases in participants with:

-IBD stratified by condition and age

-RA, stratified by age

-RA or IBD, stratified by condition (in those receiving second dose >=4 weeks after first dose and those receiving second dose >6 months after first dose)

-RA and IBD (from 1st dose)

Incidence rate of HZ in participants with:

-IBD, stratified by condition and age

-RA, stratified by age

-RA or IBD, stratified by condition (in those receiving second dose >=4 weeks

after first dose and those receiving second dose >6 months after first dose)
-RA and IBD (from 1st dose)
Number of incident IBD flare cases stratified by condition

Data analysis plan

For the VE analyses, the number and characteristics of individuals in each cohort will be described and compared. Overall incidence rates of HZ for the 2-dose (4 weeks to 6 months) 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. Adjusted 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. VE will be calculated from the hazard ratio (HR) obtained from Cox regression analysis.

For the primary safety analyses, characteristics of individuals with RA or IBD who meet inclusion criteria will be described.

Incidence rates for RA or IBD (UC or CD) flare for risk periods and comparison periods will be calculated by dividing the number of flares by person-time. Relative risks (95% CI) for flare comparing risk and comparison periods overall and by first dose and second dose will be estimated using conditional Poisson regression.

Data management

Data sources

Data source(s), other

Kaiser Permanente Health Connect 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