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Non-interventional (observational) post-licensure study to assess the effectiveness and safety of recombinant zoster vaccine in adults aged =18 years with psoriasis or psoriatic arthritis (EPI-ZOSTER-045 VE US 216976)

First published:
20/10/2023
Last updated 06/09/2024
Study
Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/108334

EU PAS number

EUPAS107230

Study ID

108334

DARWIN EU® study

No

Study countries

United States

Study description

This is 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 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:
06/12/2022
Actual:
06/12/2022

Study start date

Planned:
09/11/2023
Actual:
09/11/2023

Date of final study report

Planned:
26/06/2026

Sources of funding

Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

Protocol Anonymized_216976.pdf(1.65 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 estimate the vaccine effectiveness of 2 doses of recombinant zoster vaccine (RZV) in preventing Herpes Zoster (HZ) in Southern California adults ?18 years of age with psoriasis (PsO).
• To assess the rate of flares within 30 days following RZV vaccination as compared to the rate in self-controlled comparison periods, in Southern California adults ?18 years of age with PsO.

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

Medical condition to be studied

Psoriasis

Additional medical condition(s)

Psoriatic arthritis

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

12802

Study design details

Outcomes

Vaccine effectiveness in preventing HZ in Southern California participants with PsO. Rate of flares in Southern California participants with PsO. Vaccine effectiveness in preventing HZ in South California participants with:
- PsO or PsA (2 doses of RZV),
- PsA (2 doses of RZV),
- PsO (1 dose of RZV),
- PsA (1 dose of RZV).

Baseline characteristics in Southern California participants with:
- PsO (2 doses of RZV),

- PsA (2 doses of RZV).

Rate of flares in Southern California participants with:
- PsO or PsA,
- PsA.

Data analysis plan

Baseline demographic and clinical characteristics of individuals with PsO or PsA, who meet the inclusion criteria will be described. Categorical variables will be presented as absolute numbers and percentages for each cohort. Continuous variables such as age in years will be presented as the mean with standard deviation and/or median with interquartile ranges. For vaccine effectiveness objectives, incidence rates of HZ will be assessed for the PsO and PsA cohort. Unadjusted and adjusted vaccine effectiveness will be calculated using hazard ratios, which will be estimated by Cox proportional hazards regression models with and without adjustment for potential confounders. For safety objectives, rates of PsO or PsA flare for risk periods and comparison periods will be calculated. Incidence rate ratio comparing the rate of flares in the risk and comparison periods 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