

# A retrospective matched cohort study on the association between herpes zoster vaccination and dementia and mild cognitive impairment using electronic health records (ZOSTER-122 AIML 222419)

**First published:** 24/10/2023

**Last updated:** 18/12/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS107206

---

### Study ID

108337

---

### DARWIN EU® study

No

---

### Study countries

United States

---

## Study description

A study to determine the association between herpes zoster (HZ) vaccination and dementia and mild cognitive impairment using electronic health records.

---

## 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 GSK Clinical Trials RD.CTT-  
globalmailbox@gsk.com

Study contact

[RD.CTT-globalmailbox@gsk.com](mailto:RD.CTT-globalmailbox@gsk.com)

### Primary lead investigator

Call Center EU GSK Clinical Trials

## Study timelines

### **Date when funding contract was signed**

Planned: 13/10/2023

Actual: 13/10/2023

---

### **Study start date**

Planned: 24/10/2023

Actual: 24/10/2023

---

### **Date of final study report**

Planned: 19/09/2025

Actual: 05/08/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## 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:**

Disease /health condition  
Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Hypothesis testing

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

To determine if there is an association between either or both ZOSTAVAX and SHINGRIX and dementia primary or mild cognitive impairment (MCI) secondary using the same large scale, US electronic health record (EHR) database.

### Study Design

## Non-interventional study design

Cohort

## Study drug and medical condition

### Medicinal product name

SHINGRIX

ZOSTAVAX

---

### Medicinal product name, other

PNEUMOVAX 23

---

### Study drug International non-proprietary name (INN) or common name

CROTALINE ANTIVENIN, POLYVALENT

HERPES ZOSTER NOSODE D12

HERPES ZOSTER VACCINE (RECOMBINANT, ADJUVANTED)

---

### Anatomical Therapeutic Chemical (ATC) code

(J07BK02) zoster, live attenuated

zoster, live attenuated

(J07BK03) zoster, purified antigen

zoster, purified antigen

---

### Medical condition to be studied

Herpes zoster

Dementia

Cognitive disorder

## Population studied

## Age groups

- Adults (46 to < 65 years)
  - Elderly ( $\geq$  65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)
- 

## Estimated number of subjects

10000000

## Study design details

### Outcomes

Dementia, Mild cognitive impairment (MCI)

---

### Data analysis plan

Matched cohorts defined by their exposure to various elective adult immunizations and control conditions will be compared in pairwise fashion. For each comparison pair, the following will be reported:

- Relative risk (RR) between cumulative hazards in the compared cohorts estimated by Nelson-Aalen method at 3- and 5-years post-exposure.
- Statistical significance test results (p-value) of comparing the cumulative hazard distributions between the compared cohorts at 3- and 5-years post-exposure using Chi2 test accounting for censoring (two-sided,  $\alpha = 0.05$ ).
- Pre- and post-matching descriptive cohort statistics covering covariates, outcomes and matching factors.
- Cumulative hazard curves (y-axis: cumulative hazard, x-axis: time) for both comparison groups estimated by Nelson-Aalen including confidence intervals to enable qualitative analysis.

## Data management

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data source(s), other**

Optum Electronic Health Records (EHR) database (United States)

---

### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

[Other](#)

---

### **Data sources (types), other**

Routine primary care electronic patient registry

## 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