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: 08/08/2025





# 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**

Ongoing

## 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

### **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

# 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 topic:**

Disease /health condition

#### 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

#### Name of medicine

**SHINGRIX** 

#### Name of medicine, 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 (≥ 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

**ENCePP Seal** 

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**

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## **Check stability**

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No