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: 08/05/2025

Study   Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/108337

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

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: 31/07/2025

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

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

ZOSTAVAX

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

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