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
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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 institution and networks

Institutions

GlaxoSmithKline (GSK)

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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:
13/10/2023
Actual:
13/10/2023

Study start date
Planned:
24/10/2023
Actual:
24/10/2023

Date of final study report
Planned:
31/08/2024

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 type:
Non-interventional study

Scope of the study:
Other

If ‘other’, further details on the scope of the study
Hypothesis testing

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
(J07BK03) 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