Investigating the effect of the 13-valent pneumococcal conjugate vaccine on major adverse cardiovascular events among Medicare enrollees aged ≥65 years in the United States

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Study Planned

Administrative details

EU PAS number

EUPAS1000000520

Study ID

1000000520

DARWIN EU® study

No

Study countries

☐ United States

Study description

This retrospective observational study was designed to evaluate the effect of PCV13 on major adverse cardiovascular events (MACE) outcomes among adults aged ≥65 years in the United States using a large claims database from the Medicare health insurance program.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Amanda Courtney Miles

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 21/05/2024

Actual: 21/05/2024

Study start date
Planned: 15/04/2025

Date of final study report
Planned: 01/04/2026

Study protocol

B1851222_Non-Interventional Study Protocol_V1.0_28MAR2025 FINAL_Redacted.pdf(1.42 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Study design:

This structured secondary data collection study will be a retrospective cohort study using Centers for Medicare and Medicaid Services (CMS) Medicare data to examine the effect of PCV13 receipt on the risk of MACE among adults aged ≥65 years in the United States.

Main study objective:

Evaluate the effect of PCV13 receipt on the risk of major adverse cardiovascular events (MACE) at 1 and 3 years of follow-up among adults aged ≥65 years.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

PREVENAR 13

Medical condition to be studied

Pneumonia

Cardiovascular disorder

Population studied

Short description of the study population

The study cohort will be identified using administrative claims. The study population includes individuals aged ≥65 years of age and enrolled in Medicare Fee-for-Service (FFS) Parts A and B as of September 14, 2014. Individuals are required to have at least 6 months of prior continuous enrollment in Medicare FFS Parts A and B as of the index date to be included in the study. Individuals with evidence of PCV13 receipt prior to index, evidence of PPSV23 receipt in the 365 days prior to index, enrollment in Medicare Part C between September 14, 2014 and index, a high-risk condition for CAP in the 365d prior to index, iatrogenic immunosuppression in the 6 months prior to index, a pneumonia diagnosis code in the hospital setting in the 365d prior to index, or a MACE event in the hospital, skilled nursing facility (SNF), or long-term care facility (LTCF) setting in the 365d prior to index will be excluded. PCV13 vaccinated time segments are excluded if the individual had a pneumonia diagnosis code

in the hospital setting or a MACE diagnosis code in the hospital, SNF, or LTCF setting in the 13 days after PCV13 vaccination. For PCV13 vaccinated individuals contributing unvaccinated and vaccinated time segments, inclusion/exclusion criteria and baseline characteristics will be assessed separately for each index date.

Age groups

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

The study period is September 14, 2014 through December 31, 2019. However, Medicare data will be used going back to 1) September 14, 2013 to assess baseline characteristics and 2) January 1, 2010 to ascertain whether the individual received a PCV13 or PPSV23 vaccine prior to the study period.
The study population includes individuals aged ≥65 years and enrolled in Medicare Fee-for-Service (FFS) Parts A and B as of September 14, 2014. Individuals are required to have at least 6 months of prior continuous enrollment in Medicare FFS Parts A and B as of the index date to be included in the study. Individuals with evidence of PCV13 receipt prior to the index date, evidence of PPSV23 receipt in the 365 days prior to the index date, enrollment in Medicare Part C between September 14, 2014 and the index date, a high-risk condition for CAP in the 365 days prior to index, iatrogenic immunosuppression in the 6 months prior to index, a pneumonia diagnosis code in the hospital setting in the 365 days prior to index, a MACE event in the hospital, skilled

nursing facility (SNF), or long-term care facility (LTCF) setting in the 365 days prior to index will be excluded. PCV13 vaccinated individuals with a pneumonia diagnosis code in the hospital setting or a MACE diagnosis code in the hospital, SNF, or LTCF setting in the 13 days following first PCV13 vaccination will also be excluded.

Data analysis plan

The analyses will be conducted separately at 1 year and 3 years of follow-up. Descriptive statistics will be used to summarize baseline characteristics by vaccination group before and after propensity score weighting. Categorical variables will be summarized using frequency counts and percentages. Continuous variables will be summarized using mean, standard deviation, median, 25th and 75th percentile, minimum, and maximum.

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

The Medicare administrative claims database includes individuals ≥65 years of age and individuals with a qualifying disability who are enrolled in a Medicare

FFS plan in the United States. The database includes enrollment information for these individuals and adjudicated claims for inpatient care, ambulatory care, and outpatient prescriptions. Medicare FFS Parts A, B, and D administrative claims data is currently available from 2010 through March 30, 2024 and Medicare Part C data is available from 2015 – 2021. Several studies and systematic reviews have demonstrated the validity of using administrative data in the United States to identify MACE events.

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

Unknown