A Test-Negative Case-Control Study to Evaluate the Effectiveness of V116, CAPVAXIVE™ Against Pneumococcal Pneumonia in Older Adults

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000640

Study ID

1000000640

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ United States

Study description

The main objective of this study is to assess the effectiveness of CAPVAXIVE™ in preventing hospitalized, confirmed community acquired pneumonia (CAP) (invasive and noninvasive) caused by S pneumoniae serotypes contained in CAPVAXIVE™ and/or cross-reactive serotypes 6C and 15B among participants who received no other pneumococcal vaccines than CAPVAXIVE™ in the previous 5 years.

Study status

Ongoing

Research institutions and networks

Institutions

Merck Sharpe & Dohme LLC

IQVIA, Inc

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC
ClinicalTrialsDisclosure@msd.com

Study contact

ClinicalTrialsDisclosure@msd.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/04/2022

Actual: 22/04/2022

Study start date

Planned: 30/09/2025

Actual: 02/10/2025

Data analysis start date

Planned: 30/04/2029

Date of final study report

Planned: 31/12/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is a non-interventional study using primary and secondary data collection obtained from participants at site-based clinical primary data collection centers with real world data from electronic health records (EHR), claims and vaccine

registries with CAP.

Main study objective:

To assess the effectiveness of CAPVAXIVE™ in preventing hospitalized, confirmed CAP (invasive and non-invasive) caused by S pneumoniae serotypes contained in CAPVAXIVE™ and/or cross-reactive serotypes 6C and 15B among participants who received no other pneumococcal vaccines than CAPVAXIVE™ in the previous 5 years.

Study Design

Non-interventional study design

Case-control

Other

Non-interventional study design, other

Data Collection Study

Study drug and medical condition

Medicinal product name

CAPVAXIVE

Anatomical Therapeutic Chemical (ATC) code

(J07AL02) pneumococcus, purified polysaccharides antigen conjugated pneumococcus, purified polysaccharides antigen conjugated

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Medical condition to be studied

Pneumonia pneumococcal

Population studied

Short description of the study population

Participants who are 65 years or older with confirmed CAP by clinical signs and symptoms and radiography will be the source population for case and control identification.

Age groups

- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

Estimated number of subjects

22000

Study design details

Setting

Adult participants, 65 years or older hospitalized with CAP included in site-based clinical primary data collection centers with real world data from electronic health records (EHR), claims and vaccine registries.

Comparators

For the primary objective, the controls will be defined as confirmed CAP for whom CAPVAXIVE™ serotypes and cross-reactive serotypes 6C and 15B are not identified by any method.

For the secondary objective, the controls will be defined as confirmed non-bacteremia CAP for whom CAPVAXIVE™ serotypes and cross-reactive serotypes

6C and 15B are not identified by any method.

Controls are participants with confirmed CAP for whom CAPVAXIVE™ and cross-reactive serotypes 6C and 15B are not identified by any method.

Outcomes

The primary outcome measure is to assess the effectiveness of CAPVAXIVE™ in preventing hospitalized, confirmed CAP (invasive and non-invasive) caused by S pneumoniae serotypes contained in CAPVAXIVE™ and/or cross-reactive serotypes 6C and 15B among participants who received no other pneumococcal vaccines than CAPVAXIVE™ in the previous 5 years.

The Secondary outcome measure is to assess the effectiveness of CAPVAXIVE™ in preventing hospitalized, confirmed non-bacteremia pneumococcal pneumonia (NBPP) (confirmed CAP with absence of S pneumoniae in blood culture or culture from other sterile sites) caused by S pneumoniae serotypes contained in CAPVAXIVE™ and/or cross-reactive serotypes 6C and 15B among participants who received no other pneumococcal vaccines than CAPVAXIVE™ in the previous 5 years.

Data analysis plan

The primary outcome measure will be calculated using logistic regression, odds ratios (OR) with 95% confidence interval (CI) will be estimated adjusting for potential confounders.

The vaccine effectiveness (VE) will be expressed as a percentage and estimated as 1 minus the adjusted OR multiplied by 100. The OR will be the odds of vaccination with CAPVAXIVE™ among the cases (ie, confirmed CAP cases with any of the CAPVAXIVE™ serotypes and/or cross-reactive serotypes 6C and 15B) relative to the odds of vaccination with CAPVAXIVE™ among the test-negative controls (ie, confirmed CAP cases for whom CAPVAXIVE™ serotypes and cross-

reactive serotypes 6C and 15B are not identified).

The secondary outcome measure analysis will be conducted in the same manner as for the primary objective, but on NBPP participants meeting the inclusion and exclusion criteria for this objective (similar to those for the first objective, in particular with respect to vaccination history).
VE against confirmed VT-NBPP will also be expressed in percent and estimated as 1 minus the OR multiplied by 100.
Crude and adjusted ORs will be presented. The OR will be the odds of vaccination with CAPVAXIVE™ among the cases (ie, confirmed NBPP cases with any of the CAPVAXIVE™ serotypes and/or cross-reactive serotypes 6C and 15B) relative to the odds of vaccination with CAPVAXIVE™ among the test-negative controls (ie, confirmed non-bacteremic CAP cases for whom CAPVAXIVE™ serotypes and cross reactive serotypes 6C and 15B are not identified).

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 sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Vaccination 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

Unknown