A Phase 4 Observational, Real-World Study of 20-valent Pneumococcal Conjugate Vaccine Effectiveness Against Vaccine-Type Invasive Pneumococcal Disease in Adults Aged 65 years and above

First published: 27/03/2024

Last updated: 04/05/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000007

Study ID

1000000007

DARWIN EU® study

No

Study countries

Czechia

Israel

Spain

Study description

Multicountry observational study assessing real-world effectiveness of PCV20 against vaccine-type invasive pneumococcal disease in adults ≥65 years, using surveillance data to inform interim and final regulatory decisions.

Study status

Ongoing

Research institutions and networks

Institutions

P95 Clinical and Epidemiology Services

Belgium
Colombia
Netherlands
South Africa
Thailand
United States

First published: 07/11/2022

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Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

Networks

IPD-VEN

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 01/06/2024

Actual: 12/07/2024

Study start date

Planned: 01/09/2024

Actual: 01/01/2026

Data analysis start date
Planned: 30/04/2026

Date of interim report, if expected
Planned: 31/03/2027

Date of final study report
Planned: 30/12/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

Pfizer_Adult_PCV20_EMA Study protocol_V3.0_03Feb2026.pdf (1.38 MB)
Pfizer_PCV20_EMA Study protocol_v1.1_02JUL2024_clean (1).pdf (1.26 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

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:

No individual level data collected for the purpose of the study

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Study design:

A multi-country observational study using the indirect cohort (Broome) method will be conducted, in which cases are IPD caused by vaccine serotypes and controls are IPD caused by non-20vPnC serotypes.

Main study objective:

To estimate vaccine effectiveness of 20vPnC against IPD due to any of the 20 serotypes that are included in the vaccine (20vPnC serotypes), in adults aged 65 years and above.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medicinal product name

PREVENAR 20

Medicinal product name, other

Prevenar 20

Anatomical Therapeutic Chemical (ATC) code

(J07AL) Pneumococcal vaccines

Pneumococcal vaccines

(J07AL02) pneumococcus, purified polysaccharides antigen conjugated

pneumococcus, purified polysaccharides antigen conjugated

Medical condition to be studied

Severe invasive streptococcal infection

Additional medical condition(s)

Invasive pneumococcal disease (IPD)

Population studied

Short description of the study population

Adults aged 65 years and above with IPD with an identified pneumococcal serotype who were reported to the study site surveillance system and were

eligible for 20vPnC vaccination, according to local vaccination policies.

Age groups

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

Study design details

Setting

Study sites are national or regional surveillance systems, or hospital research networks, selected based on existing 20vPnC recommendation in adults, expected vaccine uptake, expected number of serotyped IPD cases, and availability of data on vaccination status. IPD data for all adults aged 18 years and above will be collected to monitor serotyping distribution. Participating sites will contribute up to four years of data.

Comparators

NA

Outcomes

Primary outcome will be IPD due to any of the 20vPnC serotypes;
Secondary outcomes: IPD due to any of the 13vPnC serotypes; and IPD due to any of the 7 20non13vPnC serotypes

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Data analysis plan

Study sites will submit a de-identified dataset to the study sponsor (P95). Descriptive statistics for every site and pooled for all sites will be performed. For every objective, unadjusted and adjusted VE against vaccine serotype IPD

will be estimated as VE = (1-odds ratio (OR)) x 100%, where OR denotes the odds ratio, comparing the odds of vaccination among vaccine serotype IPD (cases) to the odds of vaccination among non-vaccine serotype IPD (controls). VE estimates will be adjusted for the major confounding factors (i.e., study site, year of IPD diagnosis, age). Previous pneumococcal vaccination will be considered in the analysis. VE pooled estimates will be stratified by age group and time since 20vPnC vaccination (e.g., <2 years, 2-5 years after vaccination).

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

Data sources per IPD patient, including serotyping, patient-level information and exposure ascertainment will differ across study sites and may include national/regional IPD surveillance system, patient medical records, and vaccination registries. Study sites will submit a de-identified dataset to the study sponsor.

Data sources (types)

Non-interventional study

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