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

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000007

EU PAS number

EUPAS1000000007

Study ID

1000000007

DARWIN EU® study

No

Study countries

- ☐ Czechia
- ☐ Israel
- ☐ Spain

Study status

Planned

Research institutions and networks

Institutions

P95 Clinical and Epidemiology Services

- ☐ Belgium
- ☐ Colombia
- ☐ Netherlands
- ☐ South Africa
- ☐ Thailand
- ☐ United States

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

Contact details

Study institution contact

Germaine Hanquet

Study contact

germaine.hanquet@p-95.com

Primary lead investigator

Germaine Hanquet

Primary lead investigator

ORCID number:

0000-0002-3382-0211

Study timelines

Date when funding contract was signed
Planned: 01/06/2024

Study start date
Planned: 01/09/2024

Date of final study report
Planned: 31/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

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 2 (specific obligation of marketing authorisation)

Regulatory procedure number

EMEA/H/C/005451

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

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

Name of medicine

APEXXNAR

Name of medicine, 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

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.

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