

An Active Safety Surveillance Study for Prevenar 13® Among Chinese Children

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Study

Planned

Administrative details

EU PAS number

EUPAS1000000617

Study ID

1000000617

DARWIN EU® study

No

Study countries



China

Study description

This is a non-interventional safety active surveillance study using a population-based electronic health record (EHR) database. The observational, uncontrolled, descriptive study design will be implemented to estimate the incidence of

seizures (including febrile seizures), urticaria, angioedema, fever, thrombocytopenic purpura (TP), immune thrombocytopenia (ITP), Henoch-Schonlein purpura (HSP), anaphylaxis/anaphylactic reaction, laryngeal oedema, and Arthus reaction in the predefined risk interval for each outcome. The study period of EHR data reviewed will depend on data availability in the selected EHR databases, which could satisfy the sample size estimated for this study.

Study status

Planned

Contact details

Study institution contact

Siyan Zhan siyan-zhan@bjmu.edu.cn

Study contact

siyan-zhan@bjmu.edu.cn

Primary lead investigator

Siyan Zhan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/09/2026

Study start date

Planned: 31/12/2026

Date of final study report

Planned: 31/10/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

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:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Observational, uncontrolled, descriptive study design for non-interventional active safety surveillance based on population-based EHR databases

Main study objective:

To estimate the incidence rates of safety outcomes of interest (SOIs), including seizures (including febrile seizures), urticaria, angioedema, fever, TP, ITP, HSP, and anaphylaxis/anaphylactic reaction, laryngeal oedema, and Arthus reaction, for a prespecified risk period after Prevenar 13 vaccination (ie, risk interval), among Chinese infants and children 6 weeks through 5 years of age for all doses and for each dose.

Study drug and medical condition

Medicinal product name

PREVENAR 13

Population studied

Short description of the study population

Infants and children 6 weeks through 5 years of age who received at least 1 dose of Prevenar 13 and were recorded in the selected EHR databases in the selected study period

Study design details

Setting

The study population will include eligible infants and children 6 weeks through 5 years of age who received at least 1 dose of Prevenar 13 and were recorded in the selected EHR databases during the study period. Eligible children are followed for SOIs in the selected regional health information platform (RHIP) from the date of their first dose of Prevenar 13 vaccination until the SOI-related risk interval or SOI-related predefined monitoring period (which is 6 months after vaccination for TP, ITP, HSP, and Arthus reaction) after the last dose of Prevenar 13, moving out of the district, death, or the end of the study (whichever occurs first).

Data analysis plan

All analyses for the study will be descriptive. Incidence rates per 100,000 person-days (or 10,000 person-days) at risk and per 100,000 doses (or 10,000 doses), and the 95% CIs for the safety outcomes of interest (SOI), will be calculated for the SOI-related risk intervals after vaccination for all doses and for each dose. Analyses will be conducted separately for each regional database. Incidence of each SOI from the selected regional databases will be further summarized using meta-analysis, where appropriate. Additional analyses (eg, stratification by gender, residency, and coadministration of other vaccines) may be performed.

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)

[Electronic healthcare records \(EHR\)](#)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

No