A Pregnancy Registry Study to Evaluate the Safety of PENBRAYA™ Meningococcal Vaccine Exposure During Pregnancy

First published: 02/05/2024

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000078

Study ID

1000000078

DARWIN EU® study

No

Study countries

☐ United States

Study description

PENBRAYA (Neisseria meningitidis Groups A, B, C, W, and Y Vaccine; MenABCWY) is a pentavalent meningococcal vaccine composed of 2 licensed meningococcal vaccines: Trumenba® (N meningitidis serogroup B bivalent recombinant lipoprotein 2086 vaccine [bivalent rLP2086, also referred to as MenB-fHbp]) and Nimenrix® (meningococcal polysaccharide groups A, C, W, and Y tetanus toxoid conjugate vaccine [MenACWY-TT]).

On 20 October 2023, the United States (US) Food and Drug Administration (FDA) approved PENBRAYA for the prevention of meningococcal disease caused by meningococcal groups A, B, C, W, and Y in adolescents and young adults 10 through 25 years of age. As part of the PENBRAYA pharmacovigilance plan and in fulfillment of a post-marketing commitment (PMC) requested by the Center for Biologics Evaluation and Research (CBER), this noninterventional study (NIS) is being conducted to evaluate the safety of PENBRAYA exposure during pregnancy in a real-world setting.

The research question is: What is the risk of maternal, neonatal, or infant safety outcomes
among individuals exposed to PENBRAYA during pregnancy?

The specific objective is: To estimate the proportion of major congenital malformation (MCM), spontaneous abortion (SAB), elective termination, stillbirth, preterm birth, and small for gestational age (SGA) among individuals exposed to PENBRAYA during pregnancy or within 30 days prior to last menstrual period (LMP).

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Last updated: 01/02/2024

Institution

Pharmaceutical Product Development (PPD)

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Institution

Contact details

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Study contact

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Primary lead investigator

Cherise Wong

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/12/2023

Actual: 28/12/2023

Study start date
Planned: 30/04/2024

Actual: 03/05/2024

Date of interim report, if expected
Planned: 30/04/2025

Date of final study report
Planned: 30/04/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer 100%

Study protocol

C3511007_PROTOCOL_v1_24JAN2024.pdf(1.04 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

C3511007

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:

Primary data collection

Study design:

This registry-based, prospective, observational cohort study will enroll and follow pregnant individuals 10-25 years of age in the US who are exposed to PENBRAYA during pregnancy. Data will be collected from enrolled pregnant individuals and the healthcare providers (HCPs) involved in their care.

Main study objective:

To estimate the proportion of major congenital malformation (MCM), spontaneous abortion (SAB), elective termination, stillbirth, preterm birth, and small for gestational age (SGA) among individuals exposed to PENBRAYA during pregnancy or within 30 days prior to last menstrual period (LMP).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

PENBRAYA (meningococcal groups A, B, C, W and Y vaccine)

Medical condition to be studied

Stillbirth

Additional medical condition(s)

Congenital malformation (MCM), spontaneous abortion(SAB), elective termination, preterm birth, and small for gestational age (SGA)

Population studied

Short description of the study population

The study population will include a single cohort of pregnant individuals in the US exposed to PRENBAYA during pregnancy.

Age groups

In utero

Paediatric Population (< 18 years)

Neonate

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

50

Study design details

Setting

The study population will be derived from eligible individuals in the US enrolled in the pregnancy registry. The virtual registry coordinating center (VRCC) will coordinate enrollment and data collection. Pregnant individuals will be identified in the US during the study period using an active, targeted, multi-pronged recruitment campaign.

Outcomes

Outcomes of interest: major congenital malformation (MCM), spontaneous abortion (SAB), elective termination, stillbirth, preterm birth, and small for gestational age (SGA). For outcomes not reported by the HCP, additional information on outcome ascertainment is provided.

Data analysis plan

Demographic and baseline characteristics will be summarized with descriptive statistics for the study population.

The number of observations, median, mean, standard deviation, minimum, and maximum will be reported for each continuous variable. The frequency and percentage per category will be reported for each categorical variable. Proportion of the outcomes of interest will be calculated according to the conventions described in protocol Table 4. In general, the proportion of each outcome will be calculated by dividing the number of cases of the outcome by the appropriate denominator for that particular outcome, based on clinical knowledge. For most outcomes, the analysis population (denominator) will be the number of pregnant individuals with pregnancy outcome data, the number of live births, or the number of infants with follow-up data at the timepoint of interest, as appropriate; however, for some outcomes, the analysis population (denominator) will be restricted based on certain relevant factors (as noted in Table 4). If sample size permits, subgroup analyses will be conducted that

consider timing of exposure (earliest trimester of exposure), extent of exposure (cumulative vaccine doses during pregnancy, or relevant exposure window), and maternal age group at conception (10 to <18, 18 to 25 years). Supplementary analyses will be conducted that include pregnant individuals who were excluded from the analysis population due to occurrence of the pregnancy outcome prior to enrollment (retrospectively enrolled participants) or exposure to a known teratogen or an investigational medication during or prior to pregnancy (teratogen/investigational medication-exposed participants). Sensitivity analyses of major congenital malformation that applies a stricter definition of prospective enrollment and that restricts the preconception exposure window to 28 days prior to conception rather than 30 days prior to last menstrual period will also be conducted.

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

This will be a new, product-based pregnancy registry conducted by PPD (part of Thermo Fisher Scientific).

Data sources (types)

Other

Data sources (types), other

Primary data collection

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