Pregnancy and birth outcome assessment in a population-based cohort after exposure to Trumenba

First published: 12/12/2017

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21984

Study ID

44934

DARWIN EU® study

No

Study countries

United States

Study description

This population based cohort study is designed to assess pregnancy and birth outcomes following accidental or planned exposure to vaccination with Trumenba up to 28 days prior to or during pregnancy using electronic healthcare data in the United States (US).

Study status

Finalised

Research institutions and networks

Institutions

Harvard Pilgrim Health Care Institute

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Institution

Contact details

Study institution contact

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Study contact

Cynthia.DeLuise@pfizer.com

Primary lead investigator

Cynthia de Luise

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 07/09/2017

Actual: 05/09/2017

Study start date
Planned: 30/06/2021

Actual: 30/06/2021

Data analysis start date
Planned: 14/07/2021

Date of final study report
Planned: 31/12/2021

Actual: 16/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B1971052 Protocol Amendment 1, 20 March 2017 Clean.pdf (1.06 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The study will examine the risk of pregnancy outcomes and birth outcomes in women and infants, respectively, exposed to Trumenba prior to or during

pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07AH09) meningococcus B, multicomponent vaccine

meningococcus B, multicomponent vaccine

Medical condition to be studied

Pregnancy

Population studied

Short description of the study population

Women aged ≤ 49 years at the start of pregnancy and who were continuously enrolled in their healthcare system for 292 days prior to estimated start of pregnancy until pregnancy end date will be included. The 292 day period considers the 180 day period for receiving the three or two dose regimen (0, 2, 6 months or 0 and 6 months), an 84 day period (12 weeks) to account for irregular timing of vaccination schedules, and the 28 day period of exposure prior to the pregnancy. Women exposed to medications that present a known increased risk for fetal malformation will be retrospectively identified and

excluded from the analysis after the data has been obtained. A woman may experience pregnancy episodes in the study period that are classified as gestational trophoblastic disease, ectopic pregnancy, induced abortions, and unknown or of uncertain outcome. These episodes will be excluded from the analysis after the data have been obtained.
Patients must meet all of the following inclusion criteria to be eligible for inclusion in the
study:
1. Women aged ≤ 49 years at the start of pregnancy.
2. Women who were continuously enrolled in their healthcare system for at least 292 days prior to estimated start of pregnancy (e.g., date of last menstrual period) until pregnancy end date.
3. Eligible outcomes occurred between November 1, 2015 and October 31, 2020.
Exclusion Criteria:
There are no exclusion criteria for enrollment into this prospectively-designed study. However, the data will be accessed retrospectively after exposures and outcomes have occurred. As a result, excluding subjects prior to study enrollment is not applicable. After data collection is complete and the algorithm is implemented, women exposed to medications that present a known increased risk for congenital anomalies or administered another meningococcal B vaccine (other than Trumenba) 28 days prior to LMP or during pregnancy or pregnancy episodes that are classified as gestational trophoblastic disease, ectop

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Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

1.872

Study design details

Outcomes

Primary endpoints include live birth, spontaneous abortion, stillbirth and major congenital anomaly

Data analysis plan

This study will estimate the incidence of live births, spontaneous abortions, stillbirths, and prevalence of major congenital anomalies among clinically-recognized pregnant women, and will compare the occurrence of these events among Trumenba vaccine exposed women and infants with those among women and infants not exposed to the Trumenba vaccine.

Documents

Study results

b1971052-report-body.pdf (3.32 MB)

Study report

b1971052-abstract.pdf (2.34 MB)

b1971052-additional-reports.pdf (752.75 KB)

Study, other information

b1971052-additional-reports.pdf (752.75 KB)

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)

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