207221 - An observational, retrospective cohort database study to assess the safety of Boostrix (U.S. formulation), a reduced tetanus, diphtheria, acellular pertussis vaccine (Tdap), following routine immunization of pregnant women in the United States.

First published: 08/03/2018

Last updated: 16/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS22912

Study ID

44496

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of this study is to assess the safety of Boostrix administered on or after the first day of the 27th week of pregnancy by conducting a post-marketing study that will provide safety information to the public and healthcare providers. This will be one of the largest cohorts of pregnant women vaccinated with Boostrix in the U.S. Through partnership between Kaiser Permanente Southern California (KPSC) and the sponsor, GlaxoSmithKline (GSK), information about the safety of maternal vaccination with Boostrix and maternal and infant adverse events (AEs) in a community setting will be gained.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Kaiser Permanente Southern California (KPSC)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 7 centres are involved in the study

Contact details

Study institution contact

Call Center EU Clinical Trials

Vx.publicdisclosureglobal@gsk.com

Study contact

Vx.publicdisclosureglobal@gsk.com

Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/12/2017

Study start date
Actual: 13/04/2018

Data analysis start date
Actual: 13/04/2018

Date of final study report
Actual: 15/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-207221-protocol-redact.pdf (984.11 KB)

gsk-207221-protocol-redact-02.pdf (1.45 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To rule out a two-fold increase in the incidence of each of the following maternal and infant AEs: preeclampsia and/or eclampsia, intra-uterine infections such as chorioamnionitis and endometritis, small for gestational age (SGA), and preterm delivery among women vaccinated with Boostrix as compared to a historical cohort of women who were unvaccinated with any Tdap vaccine during their pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Boostrix

Medical condition to be studied

Pertussis

Population studied

Short description of the study population

The exposed and unexposed cohorts will consist of pregnant women with evidence of prenatal care and continuous membership (allowing up to a 31-day gap) at KPSC between the 1st day of the 27th week of gestation and the index (vaccination) date.

Women will be considered exposed if they received Boostrix on or after the 1st day of the 27 th week of gestation at selected ob-gyn clinics at seven medical centers throughout KPSC (vaccination period planned to begin in January 2018).

Unexposed pregnant women comprise women pregnant sometime during the approximate estimated period between 1/1/2012 and 12/31/2013 who did not receive any Tdap vaccine during pregnancy. If needed, we will consider adding additional years to increase the eligible number of unexposed pregnant women.

Gestational age will be estimated from the most reliable estimated date of delivery (EDD) which is based on the last menstrual period, the first accurate ultrasound examination, or both. Obstetric providers are recommended to reference guidelines from the American College of Obstetrics and Gynecology (ACOG) to calculate EDD. Pregnancy start date will correspond to a gestational age of 0 weeks

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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

Study design details

Outcomes

Number of subjects with each of the following maternal and infant AEs:- Preeclampsia and/or eclampsia- Intra-uterine infections such as chorioamnionitis and endometritis- Small for gestational age (SGA)- Preterm deliveryMaternal and infant AEs are identified from KPSC's EHR system using the pregnancy episode flowsheet and diagnosis codes.

Data analysis plan

For events identified any time after the index date and at delivery, crude incidence and 95% Confidence Interval(CI) for each AE for the exposed and unexposed groups will be calculated. The incidence of each maternal AE during pregnancy will be calculated separately and will consist of the total number of women with the condition in the numerator and the total person time in the denominator for the events identified any time after the index date, and for the events identified at delivery the incidence will consist of the total number of women with the condition in the numerator and the number of women for whom the condition can be assessed in the denominator. The person-year for a pregnant woman will be the time from the index date to the date of each

adverse event, end of the pregnancy, or disenrollment, whichever comes first. The adjusted relative risk with CI will be estimated by aPoisson regression model accounting for the follow-up time with adjustment for potential confounders.

Documents

Study results

gsk-207221-clinical-study-report-redact-02.pdf (5.59 MB)

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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No