An OTIS/MotherToBaby Pregnancy Registry-based observational cohort study to evaluate pregnancy and infant outcomes in individuals exposed to Boostrix as of the 1st day of the 27th week of gestation in the US (EPI-PERTUSSIS-075 VS US PR 219588)

First published: 19/06/2023
Last updated: 23/05/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/105108

EU PAS number
EUPAS105107

Study ID
105108

DARWIN EU® study
No

Study countries
United States

Study description
This study aims to determine whether risks of pregnancy and neonatal or early infancy safety outcomes are higher among pregnant people after receiving the Boostrix (Tdap) vaccine on or after the 1st day of the 27th week of pregnancy versus the non-vaccinated.

Study status
Ongoing

Research institution and networks

Institutions

University of California
First published: 01/02/2024
Last updated 01/02/2024
Institution

Networks

Organization of Teratology Information Specialists (OTIS) Network
First published: 01/02/2024
Last updated 01/02/2024
Network

Contact details

Study institution contact
Call Center EU GSK Clinical Trials
Study contact

RD.CTT-globalmailbox@GSK.com
Primary lead investigator
Call Center EU GSK Clinical Trials
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
19/05/2023

Study start date
Planned:
20/06/2023
Actual:
20/06/2023

Date of final study report
Planned:
19/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

Protocol_Anonymized.pdf(1.49 MB)

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 type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Main study objective:
The main objective of the study is to evaluate if there are increased risks for preterm birth, small for gestational age infants, or stillbirth after Boostrix vaccination on or after the 1st day of the 27th week of pregnancy when compared to a cohort of pregnancies unexposed to any Tdap vaccine during pregnancy.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine, other
Boostrix

Population studied

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
3000

Study design details

Outcomes
Proportion of preterm birth, small for gestational age infants, or stillbirth in pregnancies exposed to Boostrix vaccination on or after the 1st day of the 27th week of gestation when

compared to a cohort of individuals unexposed to any Tdap vaccine during their pregnancy. Proportion of preeclampsia/eclampsia, premature rupture of the membranes, chorioamnionitis, neonatal sepsis, neonatal death, or neonatal intensive care admission for bronchopulmonary dysplasia in pregnancies exposed to Boostrix vaccination on or after the 1st day of the 27th week of gestation when compared to a cohort of individuals unexposed to any Tdap vaccine during their pregnancy.

Data analysis plan
A stepwise approach will be used for the analysis. The initial analysis will be descriptive and unadjusted. Where numbers permit, multivariable analyses will be conducted for the analyses to adjust for possible confounders.

Data management

Data sources

Data source(s), other
OTIS MotherToBaby Pregnancy Registry United States

Data sources (types)
Other

Data sources (types), other
Prospective patient-based data collection, Exposure registry

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