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

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 institutions 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 RD.CTT-globalmailbox@GSK.com

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

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

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