201327 - Boostrix® Pregnancy Registry: a prospective, exploratory, cohort study to detect and describe any abnormal pregnancy outcomes in women intentionally or unintentionally vaccinated with Boostrix® during pregnancy or within 28 days preceding conception

First published: 25/03/2014

Last updated: 16/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50532

EU PAS number

EUPAS6086

Study ID

50532

DARWIN EU® study

No

Study countries

☐ United States

Study description

The purpose of this Registry is to detect and describe any abnormal pregnancy outcomes, including teratogenicity, in females intentionally or unintentionally exposed to Boostrix during their pregnancies in the US. The Registry requires voluntary, prospective reporting of eligible pregnancies by patients and health care providers (HCPs). Data such as vaccination with Boostrix during pregnancy or within 28 days preceding conception, potential confounding factors (such as exposure to other medications) and information related to the outcome of the pregnancy will be collected prospectively. The Registry was originally initiated on 03 May 2005, as part of a program of enhanced pharmacovigilance. Following new European Union Pharmacovigilance legislation, pregnancy registries are to be considered as post-authorization safety studies (PASS). The ongoing Registry will therefore be converted into a PASS study in Q1 2014.Exposed pregnancies reported to the Registry before the transition into a PASS (between 03 May 2005 and Q1 2014), from which data were collected and analyzed prospectively, will also be included in the analyses.Some pregnancy exposures may be reported after pregnancy outcome has been identified (retrospective reports). The Registry will capture retrospective reports, but these reports will not be included in the analyses of prospective reports.Pregnancy outcome data will be collected using questionnaires within 2 months of the estimated date of delivery (EDD) and approximately 6 months and 12 months after the EDD (for all live births for whom the contact details of their HCP will be available) to ascertain the presence of birth defects not diagnosed before, from Q1 2014 to Q3 2019.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

Call Center EU Clinical Trials

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: 14/03/2014

Study start date
Actual: 31/03/2014

Date of final study report
Actual: 07/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline Biologicals

Study protocol

201327-Protocol-redact.pdf(312.35 KB)

gsk-201327-protocol-redact.pdf(1.62 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

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

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

• To describe the characteristics of registered pregnancies (women vaccinated with Boostrix during pregnancy or within 28 days preceding conception) with any abnormal pregnancy outcomes. • To assess the proportion of registered pregnancies (women vaccinated with Boostrix during pregnancy or within 28 days preceding conception) with any abnormal pregnancy outcomes.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective study

Study drug and medical condition

Name of medicine, other

Boostrix

Medical condition to be studied

Pertussis

Population studied

Short description of the study population

The study focused on women vaccinated with Boostrix against tetanus, diphtheria, and pertussis during pregnancy or within 28 days of conception in the US.

Inclusion criteria:

- Exposure to vaccine occurs during pregnancy or within 28 days preceding conception.
- Subject is a US resident.
- A HCP is identified (name, address and phone number).
- Subject can be identified (by GSK or HCP).

Data from registered subjects will be included in the analyses if the following criterion is met:

- Pregnancy is ongoing and the outcome is unknown.

Exclusion criteria:

- Outcome of pregnancy is known at the time of initial report. Types of known outcomes include prenatal testing reports in which the results are abnormal or outside the reference range, indicating possible abnormality in the fetus. Typically, pregnancies > 16 weeks gestation will have undergone prenatal testing that can identify whether a child has congenital abnormalities.

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

Occurrence of any abnormal pregnancy outcomes in women intentionally or unintentionally vaccinated with Boostrix during pregnancy or within 28 days preceding conception. Pregnancy outcomes are further categorized as: 1) live births, 2) spontaneous abortions (i.e. pregnancy losses), 3) Elective/induced abortions and 4) Fetal deaths/Stillbirths.

Data analysis plan

Pregnancy outcomes are stratified by the trimester of exposure, with an additional stratum for preconception exposure with no subsequent administration of vaccine during pregnancy. Reports of multiple exposures during a pregnancy (i.e. multiple administrations of Boostrix) are classified by the earliest trimester of exposure. When exposure occurs before and after conception, the exposure is classified by the dose administered after conception. The calculations of risk for birth defects are made by dividing the number of infants with birth defects by the total number of infants with and without birth defects. Given the descriptive nature of this study, confidence

intervals will not be calculated. The outcomes of the study will be assessed against known rates from an external reference group for the likelihood of a safety signal warranting further investigation.

Documents

Study results

gsk-201327-clinical-study-report-redact.pdf(550.99 KB)

Study publications

Anastasia Kuznetsova, Maria Angeles Ceregido, Anne Jourquin, Laura Campora, Fer...

Data management

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based 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

No