Fluarix®/ FluLaval®/ Fluarix® Quadrivalent/FluLaval® Quadrivalent Pregnancy Registry: a prospective, exploratory, cohort study to detect and describe abnormal pregnancy outcomes in women intentionally or unintentionally vaccinated with Fluarix® or Fluarix® Quadrivalent or FluLaval® or FluLaval® Quadrivalent during pregnancy or within 28 days preceding conception

First published: 27/05/2014

Last updated: 18/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6521

Study ID

41807

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of this pregnancy registry study is to detect and describe abnormal pregnancy outcomes in women intentionally or unintentionally vaccinated with any of GlaxoSmithKline (GSK) Biologicals' seasonal Inactivated Influenza Vaccines (sIIVs): Fluarix, FluLaval, Fluarix Quadrivalent and FluLaval Quadrivalent.This study is a transition of existing ongoing pregnancy registries for Fluarix/ FluLaval/Fluarix Quadrivalent/ FluLaval Quadrivalent into one post-authorization safety study (PASS).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) to ascertain the presence of birth defects not diagnosed before, from Q2 2014 to Q2 2019.The intent of the Registry is to prospectively collect data such as vaccination with GSK sIIVs 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.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

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Study contact

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Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/05/2014

Study start date

Actual: 01/06/2014

Date of final study report

Actual: 01/05/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline (GSK) Biologicals

Study protocol

201476-Protocol-Redaction.pdf (318 KB)

gsk-201476-protocol-redact.pdf (929.95 KB)

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

Other

If ‘other’, further details on the scope of the study

Detect/describe abnormal pregnancy outcomes in women intentionally or unintentionally vaccinated with any of GlaxoSmithKline (GSK) Biologicals’ seasonal Inactivated Influenza Vaccines: Fluarix, FluLaval, Fluarix Quadrivalent and FluLaval Quadrivalent

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To describe the characteristics and proportion of prospectively reported pregnancies (women vaccinated with Fluarix or FluLaval or Fluarix Quadrivalent or FluLaval Quadrivalent during pregnancy or within 28 days preceding conception) with abnormal pregnancy outcomes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Abortion spontaneous

Stillbirth

Selective abortion

Abortion induced

Live birth

Population studied

Short description of the study population

In the US, the GSK sIIVs are indicated for prevention of disease caused by influenza A subtype viruses and type B virus lineages contained in the vaccine. GSK sIIVs are approved for use in persons 3 years of age (Fluarix) and older or 6 months of age and older (FluLaval or Fluarix Quadrivalent or FluLaval Quadrivalent). The study population included women vaccinated with any of the four GSK sIIVs during pregnancy or within 28 days preceding conception.

Inclusion criteria

A subject was included in the Registry if all the following criteria were met:

• Exposure to GSK sIIVs occurred during pregnancy or within 28 days preceding conception.

• Subject was a US resident.

• HCP was identified (name, address and phone number).

• Subject could be identified (by GSK or HCP).

Data from registered subjects were included in the analyses if the following criterion was met:

• Pregnancy was ongoing and the outcome was unknown at the time of initial report.

Exclusion criterion

Data from registered subjects were not included in the analyses if the following criterion was met:

• Pregnancy outcome was known at the time of the initial report. Types of known outcomes included prenatal testing reports in which the results were abnormal or outside the reference range, indicating possible abnormality in the fetus.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

1

Study design details

Outcomes

Occurrence of abnormal pregnancy outcomes in women intentionally or unintentionally vaccinated with Fluarix or FluLaval or Fluarix Quadrivalent or FluLaval Quadrivalent during pregnancy or within 28 days preceding conception during 2 months of and up to 12 months after the estimated date of delivery (EDD).

Data analysis plan

Pregnancy outcomes include spontaneous abortion and fetal deaths/stillbirths (pregnancy loss before and at or after 22 weeks gestation, resp), elective/therapeutic abortions and live births. The presence or absence of birth defects or other abnormalities is evaluated within each of the preceding outcome categories.Pregnancy outcomes are stratified by the (earliest) trimester of exposure, with an additional stratum for preconception exposure with no subsequent administration of vaccine during pregnancy. The calculations of risk for birth defects are made by dividing the number of infants with birth defects by the total number of infants reported. An exact 95% confidence interval is calculated using standard statistical software. 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.Spontaneous abortions without birth defects are excluded from the risk calculations.

Documents

Study results

gsk-201476-clinical-study-report-redact.pdf (8.02 MB)

Study publications

Nwoji U. Seasonal influenza vaccine exposure in pregnancy: 5-year results from ...

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)

Drug dispensing/prescription data

Drug registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective post-marketing reports and relevant scientific publications were potential sources of additional information.

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