114101 - Post-marketing safety study to assess the risk of spontaneous abortions in women exposed to Cervarix in the United Kingdom

First published: 15/07/2013
Last updated: 01/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/31662

EU PAS number
EUPAS3310

Study ID
31662

DARWIN EU® study
No

Study countries
United Kingdom

Study description
This study will assess the risk of spontaneous abortion during weeks 1-23 and weeks 1-19 of gestation, respectively, and other pregnancy outcomes, in an exposed cohort, i.e. women with last menstrual period (LMP) between 30 days before and 45 days after, or 30 days before and 90 days after any dose of Cervarix, when compared to a non-exposed cohort, i.e. women with LMP between 120 days and 18 months after the last Cervarix dose. The data collected in the Clinical Practice Research Datalink General Practitioner OnLine Database (CPRD GOLD) in the UK, will be analysed in this study.

Study status
Finalised

Research institution and networks

Institutions

Clinical Practice Research Datalink (CPRD)

United Kingdom
First published: 15/03/2010
Last updated
02/07/2019

Institution

Laboratory/Research/Testing facility

ENCePP partner

Networks

Clinical Practice Research Datalink General Practitioner OnLine Database

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:
25/09/2012

Study start date
Actual:
19/11/2012

Data analysis start date
Actual:
12/08/2013

Date of final study report
Actual:
17/03/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

EPI-HPV-018 VS UK DB (114101) Protocol Amendment 1 (14-Mar-2013)_Protocol Blinding_14 June 2013.pdf(812.11 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

Data collection methods:
Secondary data collection

Main study objective:
To assess the risk of spontaneous abortion during weeks 1 to 23 of gestation (UK definition) in women aged 15 to 25 years with the first day of last menstrual period (LMP) between 30 days before and 45 days after any dose of Cervarix.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(J07BM02) papillomavirus (human types 16, 18)

Medical condition to be studied
Human papilloma virus immunisation

Population studied

Short description of the study population
Pregnant women were defined based on exposure to Cervarix as recorded in the CPRD GOLD.
1. The exposed cohort included women with the first day of LMP: between 30 days before and 45 days after any Cervarix dose, as requested by the FDA, and between 30 days before and 90 days after any Cervarix dose, as defined in the study EPIHPV-020 and as used for the pooled analysis by Wacholder
2. The non-exposed cohort included women with the first day of LMP between 120 days

and 18 months after their last Cervarix dose (and no further Cervarix dose before the outcome)

Age groups
Adolescents (12 to < 18 years)
Adults (18 to < 46 years)

Special population of interest
Pregnant women

Estimated number of subjects
1046

Study design details

Outcomes
Occurrence of spontaneous abortion during weeks 1-23 of gestation, Occurrence of spontaneous abortion during weeks 1-19 of gestation,Occurrence of other pregnancy outcomes up to 12 months after last menstrual period,Baby’s death in the first 12 weeks of life.

Data analysis plan
The primary analysis will be the comparison of the risk of spontaneous abortion during the first 23 weeks of gestation and during the first 19 weeks of gestation in the exposed cohort and the non-exposed cohort using a Cox regression model with spontaneous abortion as the dependent variable, a dichotomous exposure as the independent variable and with age at first day of gestation as a covariate. The hazard ratio and its 95% confidence interval (CI) will be derived. The analysis will be done for two risk periods for the exposed subjects: the 30 days before to 45 days after any dose of Cervarix period and the 30 days before to 90 days after any dose of Cervarix period.For subjects with no spontaneous abortion, time-to-event will be censored at: the end of week 23 (or week 19), date of induced or therapeutic abortion, date of death, date of last available pregnancy data whichever occurs first.

Documents

Study results
114101-Clinical-Study-Report-Redact-V1.pdf(1.94 MB)

Data management

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