Post-Marketing surveillance for the safety of GARDASIL® and GARDASIL®9 in a cohort of Chinese women

First published: 10/07/2020

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47294

EU PAS number

EUPAS36132

Study ID

47294

DARWIN EU® study

No

Study countries

☐ China

Study description

This is a database study using the Ningbo Regional Health Information Platform to monitor the occurrence of autoimmune disorders and adverse pregnancy outcomes in GARDASIL® or GARDASIL®9 vaccinated women in Ningbo, China.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

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Institution

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 28/09/2020

Study start date
Planned: 01/06/2021

Actual: 15/03/2021

Data analysis start date
Planned: 31/03/2022

Actual: 14/03/2022

Date of final study report
Planned: 28/04/2023

Actual: 21/04/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

V503-055_Redacted Protocol red.pdf(9.48 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 topic:

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:

Secondary use of data

Main study objective:

To monitor within the NRHIP the diagnosis of 7 pre-specified new-onset autoimmune disorders diagnosed within up to 6 months after each dose of

GARDASIL® or GARDASIL®9 in Chinese women, and the occurrence of stillbirth and major congenital anomaly in infants of Chinese women who were inadvertently vaccinated with GARDASIL® or GARDASIL®9 up to 30 days prior to conception or anytime during pregnancy.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Safety surveillance of G4 or G9 vaccination

Study drug and medical condition

Name of medicine

GARDASIL 9

Population studied

Short description of the study population

Women between ages of 16 and 45 years old during the study period (i.e., age-eligible for vaccination with G4 and/or G9) who are residents of Ningbo, whose medical care information is available in the NRHIP, and who received at least one dose of G4 or G9 as part of routine health care. Ningbo has a population of approximately 2.8 million local female residents between the ages of 16-45

years old. Women selfpay for the 3-dose regimen of G4 or G9. For the pregnancy surveillance, the study population includes women who had pregnancy exposure to G4 or G9, and their infants.

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

50000

Study design details

Outcomes

Graves’ disease, Hashimoto’s disease, type 1 diabetes, systemic lupus erythematosus, multiple sclerosis, optic neuritis, uveitis, stillbirth and congenital anomalies.

Data analysis plan

A summary of the number of vaccinated women who received GARDASIL® and GARDASIL®9 will be provided, and this information will also be stratified by age, calendar year of vaccination, number of doses, timing between doses, and similar factors. Descriptive analysis of outcomes of interest will be reported. Counts of women with new onset autoimmune disease within 6 months after vaccination will be provided for the 7 pre-specified conditions. Counts of

stillbirths and congenital anomalies occurring in infants of women who received at least one dose of GARDASIL® and GARDASIL®9 up to 30 days priorto conception or anytime during pregnancy will also be included in the data summary. A summary of the case validation methods and results will also be provided.

Documents

Study results

V503-055 G4 G9 combined_final redaction_0.pdf(1.09 MB)

V503-055-CSR-HPV PMC G9 Safety Study Report_final redaction.pdf(789.7 KB)

Data management

Data sources

Data source(s), other

Ningbo Regional Health Information Platform China

Data sources (types)

Other

Data sources (types), other

Regional health information platform

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