Post-licensure Observational Safety Study of Gardasil 9 (V503-028)

First published: 10/05/2016

Last updated: 27/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47277

EU PAS number

EUPAS13151

Study ID

47277

DARWIN EU® study

No

Study countries

☐ United States

Study description

The V503-028 study will describe the general safety of the 9vHPV vaccine in a population of 10,000 males and females who have received at least one dose of human papillomavirus (HPV) 9-valent Vaccine (9vHPV vaccine), Gardasil 9. The general safety assessment will be conducted by estimating the risk (i.e., the incidence) of health outcomes resulting in emergency room visits or hospitalizations occurring within a pre-specified risk period after a dose of the vaccine, and comparing to the risk of such health outcomes in a post-vaccination self-comparison reference period.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

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Institution

Networks

Large managed care organization in the United States

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/08/2015

Study start date

Actual: 10/06/2016

Data analysis start date

Planned: 01/09/2019

Actual: 01/03/2019

Date of final study report

Planned: 31/12/2019

Actual: 10/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

Final_V503 PASS Study Protocol_2_final-redaction_2.pdf(224.41 KB)

Final Redactions Applied_Final_V503 PASS Study Protocol.pdf(569.11 KB)

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:

Combined primary data collection and secondary use of data

Main study objective:

The objective of this study is to describe the general safety of the 9vHPV vaccine in a population of 10,000 males and females who have received at least one dose of the 9vHPV.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective, observational self-controlled risk interval (SCRI) study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BM03) papillomavirus (human types 6, 11, 16, 18, 31, 33, 45, 52, 58) papillomavirus (human types 6, 11, 16, 18, 31, 33, 45, 52, 58)

Population studied

Short description of the study population

The study focused subjects aged 9 years or older who received at least one dose of the 9vHPV vaccine and were members of the health plan at the time of the dose. Exclusions include those who received any doses outside the health plan.

The study cohorts are divided into the 9vHPV-Only Cohort, those who initiated the vaccination and received at least one dose of the vaccine, and the Any 9vHPV Cohort, those who received at least one dose of the vaccine regardless of exposure to the 4vHPV vaccine before and had no exposure to any other HPV vaccines.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

10000

Study design details

Outcomes

Estimating the risk of health outcomes resulting in emergency room visits or hospitalizations occurring within a pre-specified risk period after a dose of the 9vHPV vaccine, and comparing to the risk of such health outcomes in a post-vaccination self-comparison reference period.

Data analysis plan

For each health outcome that results in a hospitalization or emergency room visit during the risk and/or self-comparison periods, the risk (i.e. incidence rate)

will be calculated and presented for emergency room visits and hospitalizations combined. Relative risk of health outcomes as estimated by the odds ratios and 95% confidence intervals (CI’s) will be estimated with conditional logistic regression.

Documents

Study results

V503-028-final-report_Final Redaction.pdf(1.2 MB)

Study publications

Hansen J, Yee A, Lewis N, Li S, Velicer C, Saddier P, Klein NP. Safety of 9-val...

Data management

Data sources

Data sources (types)

Disease registry

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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