A Post-licensure Surveillance Program for the Safety of GARDASIL™ in a Managed Care Organization Setting (V501-031)

First published: 04/05/2017

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17731

EU PAS number

EUPAS17730

Study ID

17731

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study describes the general safety of Gardasil™ when administered to females as part of routine medical care at a large integrated healthcare system.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

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Institution

Two large integrated healthcare systems in the United States California

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 04/11/2007

Study start date
Actual: 08/01/2007

Data analysis start date
Actual: 06/01/2008

Date of final study report
Actual: 13/12/2010

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

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)

Other study registration identification numbers and links

Study Number: V501-031NCT number: NCT01078220

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 use of data

Main study objective:

To assess the general safety of Gardasil™ when administered to females as part of routine healthcare.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational surveillance

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BM01) papillomavirus (human types 6, 11, 16, 18)

papillomavirus (human types 6, 11, 16, 18)

Medical condition to be studied

Human papilloma virus immunisation

Population studied

Short description of the study population

Females who received GARDASIL™ vaccination.

Inclusion Criteria for the Primary Populations

For Monitoring Short-Term Safety

1. a female between ages 9-26 years at the time of first dose of GARDASIL™

2. completes the series of 3-dose regimen of GARDASIL™ within 12 months of time (between the first and third doses) with at least an interval of 28 days between dose 1 and dose 2 and 12 weeks between dose 2 and dose 3.

For Evaluation of Inadvertent Exposure to GARDASIL™ During Pregnancy

1. receives at least one dose of GARDASIL™ either up to 30 days prior to the date of conception during the study period in which accrual of the primary population takes place or at any time between conception and the day the pregnancy is resolved.

For Evaluating Select Autoimmune Conditions

1. a female who has received at least one dose of GARDASIL™

2. has been a member within the same MCO for at least 12 months prior to the receipt of GARDASIL™ (for medical record review)

Inclusion Criteria for the Reference Groups

For Monitoring Short-Term Safety

1. females between ages 9-26 years at the time of first dose of GARDASIL™

Inclusion Criteria for the Secondary Short-term Safety Analysis Cohort

1. receives one or two doses of GARDASIL™; or

2. Off -label use of at least one dose of GARDASIL™

SUBJECT/PATIENT EXCLUSION CRITERIA

2.3.1 Exclusion Criteria for the Primary Populations

For Monitoring Short-Term Safety

1. males

2. receives incomplete regimen of GARDASIL™

3. completes the 3-dose regimen of GARDASIL™ in more than 12 months of

time.
4. Less than a 28 day interval between doses 1 and 2 or less than a 12-week interval between doses 2 and 3 of GARDASIL™.
5. younger than 9 or older than 26 years of age at receipt of first dose
For Evaluation of Pregnancy Safety
1. males
2. no record of pregnancy at the MCO
For Evaluating Select Autoimmune Conditions
1. have been member of the same MCO for less than 12 months prior to receiving the first dose of GARDASIL™ (for medical record review)
2. males
E

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

189629

Study design details

Outcomes

The primary outcome is incidence rates of health outcomes resulting in emergency room visits or hospitalizations following receipt of Gardasil™, compared to post-vaccination self-comparison. The secondary outcomes are:1. To provide the descriptive epidemiology of the outcomes of pregnancy exposures to Gardasil™2. To provide the descriptive epidemiology of the

outcomes of 16 pre-specified new onset autoimmune conditions after receipt of Gardasil™

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 incidence rates will be calculated and the relative risk of health outcomes as estimated by the odd ratios and 95% confidence intervals will be estimated with conditional logistic regression.

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