Post-Licensure Observational Study of the Safety of GARDASIL(TM) in Males (V501-070)

First published: 01/06/2017

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50012

EU PAS number

EUPAS17675

Study ID

50012

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a post-licensure observational cohort study to describe the general safety of GARDASIL(TM) in males by estimating the rate of health outcomes resulting in an emergency room visit or hospitalization in a pre-defined risk period after vaccination, the rate of specific events (e.g. syncope, epilepsy, convulsions, and allergic reactions) on the day of vaccination, and the rate of new-onset autoimmune conditions after vaccination.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

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Institution

Networks

Large healthcare claims database 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: 06/04/2010

Study start date

Actual: 23/06/2011

Data analysis start date

Planned: 01/06/2019

Actual: 01/06/2019

Date of interim report, if expected

Actual: 09/12/2016

Date of final study report

Planned: 31/12/2019

Actual: 28/06/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.

Study protocol

V501-070-01 Protocol Summary.pdf(319.33 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)

Other study registration identification numbers and links

NCT01567813,V501-031

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:

This is a post-licensure observational cohort study to describe the general safety of GARDASIL(TM) in males.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Descriptive observational study

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)

Population studied

Short description of the study population

Male patients who received at least one dose of GARDASIL® identified from the Optum research database in the US from 16 October 2009 to 31 December 2016 with follow up through 31 May 2017.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

44000

Study design details

Outcomes

The primary outcome is the incidence of health outcomes resulting in an emergency room visit or hospitalization after receipt of GARDASIL(TM)compared to post-vaccination self-comparison periods. The secondary outcomes are (1) Incidence of health outcomes resulting in an emergency room visit or hospitalization following the first dose of GARDASIL(TM), (2) incidence of syncope, convulsive syncope, epilepsy, convulsions, head trauma, and allergic

reactions on the day of vaccination, and (3) incidence of new-onset autoimmune conditions.

Data analysis plan

Incidence and relative risks will be calculated for primary and secondary outcomes. Relative risks will be calculated as the ratio of the incidence of the health outcome in the risk and comparison periods. Confidence intervals (CIs) will be calculated using the mid-probability exact method.

Documents

Study results

p070v501_final-redaction.pdf(7.22 MB)

Study report

V501-070-01 Study Results-Interim Report.pdf(2.01 MB)

V501-070-supplemental-report-aug-2020_Final Redaction Pages 1-73.pdf (935.81 KB)

Study, other information

V501-070-supplemental-report-aug-2020_Final Redaction Pages 1-73.pdf (935.81 KB)

Study publications

Amend KL, Turnbull B, Zhou L, Marks MA, Velicer C, Saddier P, Seeger JD. Vaccin…

Seeger JD, Amend KL, Turnbull BR, Zhou L, Marks MA, Velicer C, Saddier P. Incid…

Amend KL, Turnbull B, Zhou L, Marks MA, Velicer C, Saddier P, Seeger JD. Safety…

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Medical chart review

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