GARDASIL(TM) Vaccine Impact in Population (VIP) Study (V501-033)

First published: 17/04/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17505

Study ID

20359

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Norway
- [ ] Sweden

Study description

This study was conducted to assess the impact of GARDASIL(TM) human papillomavirus (HPV) vaccine on the epidemiology of HPV-related genital disease in the general female population (18- to 45-year old) in participating Nordic countries. The study was based on a combination of national registry data and primary data collection that took a series of cross-sectional snap shots at the general female population in Denmark, Norway and Sweden between 2004 (before the implementation of population-based HPV vaccination) and 2012 (after this implementation). There were four components in the study, including 1) surveillance of HPV-related disease incidence (cervical, vaginal, and vulvar cancers, and their precursors), 2) pregnancy safety (i.e., prevalence of congenital anomalies in infants born to mothers with inadvertent exposure to the vaccine during pregnancy or shortly before conception), 3) HPV typing in cervical samples (to measure HPV prevalence in cervical cancer and precursor lesions, and in the general female population), and 4) questionnaire surveys (to assess life style and risk-taking sexual behavior). The first two components utilized the existing nationwide registry data in the Nordic countries while the last two components were based on cross-sectional collections of cervical samples and questionnaire survey data in the general female population.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution | Pharmaceutical company

Danish Cancer Society Denmark, The Cancer Registry of Norway Norway, Karolinska Institutet Sweden

Contact details

Study institution contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/05/2007

Study start date
Actual: 29/05/2007

Data analysis start date
Actual: 02/12/2014

Date of final study report
Actual: 19/12/2014

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

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

Disease epidemiology

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

This study was conducted to assess the impact of GARDASIL(TM) human papillomavirus (HPV) vaccine on the epidemiology of HPV-related genital disease in the general female population (18- to 45-year old) by utilizing nationwide registry databases as well as primary data collection in the participating Nordic countries.

Study Design

Non-interventional study design

Cohort

Cross-sectional

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

Genital infection female

Genital infection viral

Genital lesion

Genital neoplasm malignant female

Population studied

Short description of the study population

All female residents aged 18- to 45-year old in the participating Nordic countries.

Registry Data: All female residents in the participating Nordic countries who are/were alive on January 1 in the year the data will be used for analysis were included

Survey Data: All female residents alive in the participating countries on July 1, 2004 (baseline survey) and July 1, 2011 (post-vaccination survey) and subjects providing consent granting permission to use the questionnaire data and to linkage of the questionnaire data to other registry databases by using their

NPIN were included.

Cervical Sample Collection:

For HPV data in general female population:

• Cervical samples from residents of the participating countries collected between 2006 and 2007, or in 2011-2012 under (including) age 45.

For HPV data in lesional samples

• Cervical samples from women with a diagnosis of CIN or cervical cancer between 2004-2006 and 2011-2012.

Age groups

- Adults (18 to < 46 years)

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Estimated number of subjects

470000

Study design details

Outcomes

1. To describe the incidence of select HPV-related female genital disease before and after the introduction of GARDASIL(TM)2. To describe the prevalence of HPV infection before and after the introduction of GARDASIL(TM)3. To describe congenital anomalies in babies born to women who wereinadvertently exposed to GARDASIL(TM) during their pregnancies, 1. To describe the incidence of select HPV-related female genital disease, stratified by recipient vs. non-recipient of GARDASIL(TM)2. To examine the prevalence of HPV infection in the

general female population after the introduction of GARDASIL(TM)3. To characterize HPV vaccination in 18-45 year old females in the participating Nordic countries before and after introduction of GARDASIL(TM)

Data analysis plan

This was a descriptive study where no formal comparisons were done between the two time points (before and after the introduction of GARDASILTM), only cross-sectional estimates of the incidence of HPV-related female genital diseases, prevalence of vaccine-type and non-vaccine type HPV infection, and pregnancy safety in women with exposure to GARDASIL(TM) during pregnancy were calculated. The study was conducted in Denmark, Norway, and Sweden. Iceland was initially included in the study but had minimal uptake of GARDASIL(TM) and was subsequently excluded from analyses of the impact of GARDASIL(TM). Iceland was included in pregnancy safety evaluation.

Documents

Study publications

Hansen BT, Kjær SK, Arnheim-Dahlström L, Liaw KL, Jensen KE, Thomsen LT, Munk C...

Kjaer SK, Tran TN, Sparen P, Tryggvadottir L, Munk C, Dasbach E, Liaw KL, Nygår...

Hansen BT, Hagerup-Jenssen M, Kjaer SK, Munk C, Tryggvadottir L, Sparén P, Liaw...

Nygård M, Hansen BT, Dillner J, Munk C, Oddsson K, Tryggvadottir L, HortlundM, ...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Survey of demographic and behavior characteristicsLesional samples for HPV typingDisease/case/cancer/immunization registries

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