

# Post-Marketing surveillance for HPV infection related serious disease in a cohort of Chinese women who received GARDASIL® and GARDASIL®9

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS36135

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### Study ID

50291

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### DARWIN EU® study

No

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### Study countries

 China

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### Study description

This is a database study using the Ningbo Regional Health Information Platform (NRHIP) to monitor the occurrence of high-grade cervical intraepithelial neoplasia in GARDASIL® or GARDASIL®9 vaccinated women in Ningbo, China.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Merck Sharp & Dohme LLC

 United States

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Institution

Pharmaceutical company

## Contact details

### Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

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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

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### **Study start date**

Planned: 01/06/2021

Actual: 15/03/2021

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### **Data analysis start date**

Planned: 31/01/2022

Actual: 17/01/2022

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### **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

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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### **Main study objective:**

The primary objective is to monitor the occurrence of high-grade cervical intraepithelial neoplasia in a cohort of Chinese women who were vaccinated with GARDASIL® or GARDASIL®9 in Ningbo. The secondary objective is to monitor the occurrence of high-grade cervical intraepithelial neoplasia in a cohort of Chinese women without HPV vaccination, who are matched to the vaccinated women.

## Study Design

### **Non-interventional study design**

Cohort

Other

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### **Non-interventional study design, other**

Register-based, observational surveillance activity

## Population studied

### **Short description of the study population**

The study focused on cervical disease in Ningbo, specifically targeting female residents aged 16-45 years who received at least one dose of G4 or G9 HPV vaccine. The vaccinated cohort included eligible women who received the vaccine and have medical care information available on the Ningbo Regional Health Information Platform (NRHIP).

Inclusion criteria:

- Female residents registered in the NRHIP;
- Health data available in the NRHIP;

- Received at least 1 dose of G4 or G9 during the study period (including those with a mixed regimen of G4 and G9);
- 20 to 45 years old at initiation of G4 vaccination, or 16 to 26 years old at initiation of G9 vaccination.

Exclusion criteria:

- Women who received HPV vaccination other than G4 or G9

The unvaccinated cohort included eligible women who received no HPV vaccine and are matched based on factors like age, area of residence, and cervical HPV/cytology testing services.

Inclusion criteria:

- Female residents registered in the NRHIP;
- Health data available in the NRHIP;

Exclusion criteria:

- Women who received HPV vaccination.

The study also women from the general population aged 45 years or more to better understand the occurrence of cervical disease reported to the NRHIP.

Inclusion criteria:

- Female residents registered in the NRHIP;
- Health data available in the NRHIP.

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### **Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

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### **Estimated number of subjects**

50000

## **Study design details**

## Outcomes

High-grade cervical intraepithelial neoplasia

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### Data analysis plan

The number of high-grade cervical intraepithelial neoplasia cases in the vaccinated cohort will be tabulated and presented overall and by calendar year and age. The occurrence of high-grade cervical intraepithelial neoplasia in the matched unvaccinated cohort and general population of women will also be summarized overall, and by calendar year and age. Rates of high-grade cervical intraepithelial neoplasia occurrence in vaccinated and matched unvaccinated cohorts will be reported and compared, if methodologically feasible. Consistent with principles of Good Pharmacoepidemiology Practice (GPP), we will assess the availability, quality, completeness, comparability, and limitations of the data for each cohort. The decision to calculate and report rates and rate comparisons will be based on the results of this data assessment and guided by application of GPP principles for observational studies.

## Documents

### Study results

[V503-056-CSR- HPV PMC G9 effectiveness study report\\_final redaction.pdf](#) (1.06 MB)

[V503-056\\_Combined G4 and G9 Report with Cover Letter\\_final redaction.pdf](#) (1.29 MB)

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## 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)

Other

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### Data sources (types), other

Regional health information platform

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

No