Post-Marketing surveillance for HPV infection related serious disease in a cohort of Chinese women who received GARDASIL® and GARDASIL®9 (V503-107)

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Study Planned

Administrative details

EU PAS number

EUPAS1000001165

Study ID

1000001165

DARWIN EU® study

No

Study countries

China

Study description

The purpose of this study is to provide longer follow-up and an increased sample size for post-marketing surveillance of high-grade cervical disease among Chinese women. The main objective of the study is to monitor the occurrence of high-grade cervical intraepithelial neoplasia (CIN2/3) in women who received GARDASIL® or GARDASIL®9 and tested negative for human papillomavirus (HPV) and in matched women who did not receive HPV vaccination in Zhejiang Province, China. The study will also monitor CIN2/3 among women vaccinated with GARDASIL® or GARDASIL®9 and provide information on CIN2/3, adenocarcinoma in situ (AIS), and cervical cancer in the general female population in Zhejiang Province, China.

Study status

Planned

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Last updated: 08/07/2025

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

Planned: 31/12/2026

Study start date

Planned: 31/03/2027

Data analysis start date

Planned: 30/09/2027

Date of final study report

Planned: 31/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

v503-107-01-v1-with-ha-approval-date_final-redaction.pdf (460.45 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is an observational cohort study using secondary data from the ZVRWP to conduct post-marketing surveillance of high-grade cervical disease among women who received GARDASIL® or GARDASIL® 9, matched women who did not receive HPV vaccination, and women in the general female population in Zhejiang

Main study objective:

The main objective of the study is to monitor the occurrence of high-grade CIN2/3 in women who received G4 or G9 and tested negative for HPV, compared with matched women who did not receive HPV vaccination in Zhejiang Province, China.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

GARDASIL

GARDASIL 9

Medicinal product name, other

Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)

Human papillomavirus 9-valent vaccine (recombinant, adsorbed)

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)

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

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

Additional medical condition(s)

Cervical disease

Population studied

Short description of the study population

The study population includes women in Zhejiang Province, China, who received G4 or G9, matched women who did not receive HPV vaccination, and women in the general female population. Vaccinated women are identified from the Zhejiang Province Vaccine Real-World Research Platform (ZVRWP) beginning when G4 and G9 became available in the ZVRWP in 2017 and are followed through approximately 31 December 2026. The general female population includes women with cervical disease diagnosis data available in the ZVRWP.

Age groups

- **Paediatric Population (< 18 years)**
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)

        - Adults (18 to < 46 years)
        - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
        - Adults (65 to < 75 years)
        - Adults (75 to < 85 years)
        - Adults (85 years and over)

Study design details

Setting

Women in Zhejiang Province, China, included in the ZVRWP, including women vaccinated with G4 or G9 and matched unvaccinated women.

Comparators

Up to 3 unvaccinated women will be matched to each eligible woman in the vaccinated HPV test-negative sub-cohort based on age at enrollment (+/-1 year) and area of residence (urban/rural). The formal comparison of the rates between the vaccinated HPV test-negative sub-cohort and the matched unvaccinated cohort might not be considered meaningful due to the short follow-up period since the introduction of vaccination with G4/G9 and low coverage of cervical screening services in Zhejiang.

Outcomes

The primary outcome is the occurrence of high-grade CIN2/3, AIS, and cervical cancer in women who received G4 or G9 and tested negative for HPV, compared with matched women who did not receive HPV vaccination.

Data analysis plan

Demographics and disease characteristics will be analyzed. For continuous variables, mean, standard deviation (SD), median, interquartile range (IQR), and

range will be presented. For categorical variables, the number of patients in each category and percentage will be presented. Rates of high-grade CIN2/3, adenocarcinoma in situ (AIS), and cervical cancer in the cohorts will be estimated with 95% confidence intervals (95% CIs). For the primary and secondary objectives, analyses will be carried out using the available data. A subject with missing data for a given variable will be excluded from the analyses for that variable. No sensitivity analysis will be undertaken.

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 source(s), other

Zhejiang Province Vaccine Real-World Research Platform (ZVRWP)

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes