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

First published: 10/07/2020

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS36135

Study ID

50291

DARWIN EU® study

No

Study countries

☐ China

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.

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

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC
ClinicalTrialsDisclosure@merck.com

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: 28/09/2020

Study start date
Planned: 01/06/2021

Actual: 15/03/2021

Data analysis start date
Planned: 31/01/2022

Actual: 17/01/2022

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

V503-056_Redacted Protocol red.pdf(9.45 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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

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

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.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

50000

Study design details

Outcomes

High-grade cervical intraepithelial neoplasia

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)

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

Data sources (types), other

Regional health information platform

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