Retrospective cohort study evaluating effectiveness of GARDASIL™ against adult-onset recurrent respiratory papillomatosis in Norway

First published: 20/01/2023

Last updated: 07/04/2025

Study Cancelled

Administrative details

EU PAS number

EUPAS50387

Study ID

50697

DARWIN EU® study

No

Study countries

Norway

Study description

Study cancelled - It has been combined with study V503-088 (EUPAS48452). Recurrent respiratory papillomatosis (RRP) is a rare disease caused by human papillomavirus (HPV) infection in the airways, marked by recurrent papillomatous lesions in the respiratory tract. HPV types 6 and 11 account for over 90% of RRP cases. GARDASIL/GARDASIL 9 vaccines protect against HPV types 6, 11, 16 and 18, and were administered to 12 year old girls from 2009-2016 as part of the childhood vaccination program in Norway. The primary objective of the study is to use a population-based retrospective cohort study to assess whether vaccination with GARDASIL/GARDASIL 9 before 17 years of age reduces the risk of adult-onset RRP. The secondary objectives of the study are to use nationwide registry data to assess annual incidence rates of adult onset RRP and juvenile-onset RRP among males and females in Norway since 2008.

Study status

Cancelled

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

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: 23/11/2021

Study start date

Planned: 28/02/2023

Actual: 26/01/2023

Data analysis start date

Planned: 29/11/2024

Date of final study report

Planned: 31/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

V503-090-00-v1-Protocol_final redaction.pdf (333.09 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

The primary objective is to assess whether vaccination with GARDASIL/GARDASIL 9 before 17 years of age reduces the risk of adult-onset RRP.

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

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

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

(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)

Medical condition to be studied

Respiratory papilloma

Additional medical condition(s)

Adult-onset recurrent respiratory papillomatosis, Juvenile-onset Recurrent respiratory papillomatosis

Population studied

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

Estimated number of subjects

3.000.000

Study design details

Outcomes

Incidence of adult-onset RRP among females measured using ICD-10 code D14.1, 1) Incidence of adult-onset RRP among males and females measured using ICD-10 code D14.1 2) Incidence of juvenile-onset RRP among males and females measured using ICD-10 code D14.1.

Data analysis plan

The data will be analyzed for the primary objective using a Cox Proportional Hazards Model for the risk of first adult-onset RRP incidence, using age as running time. For the secondary objectives, age-standardized incidence rates of juvenile-onset RRP and adult-onset RRP will be calculated stratified by age group and calendar period.

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)

Norwegian Health Registers

Data source(s), other

Norwegian Patient Registry, Norway

Norwegian Immunisation Registry, Norway

Norwegian Prescription Database, Norway

Statistics Norway, Norway

Norwegian Population Registry, Norway

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Other

Data sources (types), other

Exposure registry

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