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

First published: 20/01/2023
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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/50697

EU PAS number
EUPAS50387

Study ID
50697

DARWIN EU® study
No

Study countries
Norway

Study description
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
Ongoing

Research institution and networks

Institutions

Merck & Co.
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Institution

Contact details

Study institution contact
Clinical Trials Disclosure Merck Sharp & Dohme LLC
Study contact

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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:
23/11/2021

Study start date
Planned:
28/02/2023
Actual:
26/01/2023

Data analysis start date
Planned:
28/06/2024

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

Name of medicine
Gardasil
Gardasil 9

Name of medicine, 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)
(J07BM03) 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
3000000

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

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 data (e.g. claims)
Disease registry

Drug dispensing/prescription data
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