

217743 - An observational, retrospective database post-authorisation safety study (PASS) to assess trends and changes over time in incidence of anal cancer and feasibility for a case-control study in European countries that introduced Cervarix in their National Immunisation Programmes (NIP) (EPI-HPV-099 VS EUR DB)

First published: 04/08/2021

Last updated: 01/07/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS42373

Study ID

48885

DARWIN EU® study

No

Study countries

-  Denmark
 -  Finland
 -  Netherlands
 -  Norway
 -  United Kingdom
-

Study description

The aim of this study is to assess trends and changes over time in incidence of anal cancer using data reported to the national cancer registries in Finland, the Netherlands, England, Denmark, and Norway and to carry out an assessment of feasibility to conduct a case-control study in any of these 5 European countries aiming to determine the impact and effectiveness of GSK's HPV vaccine against anal cancer in females and males.

Study status

Finalised

Research institutions and networks

Institutions

[Finnish Cancer Registry](#)

 Finland

First published: 14/09/2012

Last updated: 01/06/2018

Institution

Outdated

Other

ENCePP partner

Finnish Cancer Registry

 Finland

First published: 14/09/2012

Last updated: 01/06/2018

Institution

Outdated

Other

ENCePP partner

Public Health Evaluation and Projection/Vaccine Safety Evaluation, National Institute for Health and Welfare

 Finland

First published: 22/05/2018

Last updated: 24/10/2019

Institution

Outdated

Educational Institution

Laboratory/Research/Testing facility

ENCePP partner

The Netherlands Cancer Registry Netherlands,
National Cancer Registration and Analysis Service
UK, The Danish Cancer Registry Denmark, The

Cancer Registry of Norway Norway, Dutch
vaccination registry (Præventis) Netherlands, Child
Health Information Systems England, Danish
vaccination registry Denmark, Norwegian
vaccination registry Norway

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Eero Pukkala

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/07/2021

Study start date

Actual: 12/08/2021

Date of final study report

Actual: 27/03/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

[Redacted EPI-HPV-099 Protocol Amendment 2 Anonymized 27 Sep 2022.pdf](#)

(540.92 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition
Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess trends and changes over time in the age-standardised incidence and in the crude incidence of anal cancer by age category (in the case of crude incidence), by sex, HPV-type and histological classification for each country* separately. *Five European countries are considered for this study and each country will be selected based on a set of criteria.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational, retrospective database study

Study drug and medical condition

Medicinal product name

CERVARIX

Medical condition to be studied

Anal cancer

Population studied

Short description of the study population

The study population included males and females of all age groups identified from the national cancer registries in Finland, the Netherlands, England, Denmark, and Norway to understand the incidence of anal cancer.

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

Special population of interest

Other

Special population of interest, other

Estimated number of subjects

0

Study design details

Outcomes

Age-standardised and crude incidence of anal cancer by age category (in the case of crude incidence), by sex, HPV-type and histological classification for each country separately, incidence of small intestine cancer by age category and sex for each country separately. Number of anal cancer cases expected to demonstrate vaccine effectiveness for each country separately.

Data analysis plan

Analysis will be performed using the country-specific data extracted from the national cancer registries as per defined population and timeframe.

Documents

Study results

[Study_Report_Interim_Anonymized.pdf](#) (6.38 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)

[Disease registry](#)

[Other](#)

Data sources (types), other

Statistical Office i.e. EUROSTAT, Office for National Statistics (UK)

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