Efficacy/Effectiveness of Cervarix against grade 3 cervical intraepithelial neoplasia or worse (CIN3, CIN3+) and cervical cancer. A systematic review and meta-regression analysis (EPI-HPV-101 VE DB 221785)

First published: 01/03/2024

Last updated: 02/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000026

Study ID

1000000026

DARWIN EU® study

No

Study countries

Belgium

Study description

A study to evaluate the efficacy/effectiveness of the vaccination with GSK's bivalent HPV vaccine (Cervarix) of girls and women against HPV on cervical cancer and cervical intraepithelial neoplasia grade 3 or worse (CIN3, CIN3+).

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

Call Center EU GSK Clinical Trials RD.CTT-globalmailbox@gsk.com

Study contact

RD.CTT-globalmailbox@gsk.com

Primary lead investigator

Call Center EU GSK Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 07/09/2023

Study start date
Actual: 07/09/2023

Date of final study report
Planned: 29/02/2024

Actual: 01/03/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline (GSK)

Study protocol

Protocol_Anonymised.pdf (1.81 MB)

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:

Effectiveness study (incl. comparative)

Study design:

Systematic review and meta-regression analysis

Main study objective:

To perform a meta-regression analysis to provide estimates of the effect size of GSK’s bivalent HPV vaccine on CIN3+ while adjusting for covariates such as age at vaccination, time since vaccination (time of follow-up), or type of analytical cohort (HPV baseline status), and study design.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Medicinal product name

CERVARIX

Medicinal product name, other

human papillomavirus vaccine [types 16, 18] (recombinant, adjuvanted, adsorbed)

Anatomical Therapeutic Chemical (ATC) code

(J07BM02) papillomavirus (human types 16, 18)

papillomavirus (human types 16, 18)

Additional medical condition(s)

Human papillomavirus-related advanced cervical lesions and cervical cancer

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

Estimated number of subjects

296.000

Study design details

Outcomes

Efficacy, effectiveness, or combined efficacy/effectiveness of GSK´s bivalent vaccine on CIN3+ caused by HPV 16/18 or any HPV type.

Data analysis plan

A systematic literature review has been conducted and a quantitative synthesis of the findings was pursued to determine a summary point estimate of the long-term efficacy/effectiveness of GSK's bivalent HPV vaccine on the selected endpoints. Simple meta-analyses were first performed followed by univariate meta-regression analyses by the variables of interest, and multivariate meta-regression analyses within different scenarios.

Multiparametric meta-regressions adjusting for the following covariates: age at first vaccination, study design (randomized controlled trials vs observational), analytical cohort (Total vaccinated cohort vs Total vaccinated cohort naïve), and time since vaccination (time of follow-up). An Akaike information criterion (AIC) (estimator of prediction error) approach was used to assess the quality of the models for every given dataset allowing a data-driven selection of the best model.

Documents

Study report

Clinical_Study_Report_Anonymised.pdf (3 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 source(s), other

PubMed, United States

Embase, Netherlands

SCOPUS, Netherlands

Cochrane Central Register for Clinical Trials (CENTRAL), United Kingdom

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Data sources (types)

Other

Data sources (types), other

Medical research databases

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

Not applicable