

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

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Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1000000026>

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

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

Name of medicine

CERVARIX

Name of medicine, 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

296000

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

Data sources

Data source(s), other

PubMed, United States

Embase, Netherlands

SCOPUS, Netherlands

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

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