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 institution and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

Call Center EU GSK Clinical Trials

Study contact

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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)

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