207644 - Meta analysis of HPV-associated CIN2, CIN2+ and CIN3+ cases in efficacy studies according to baseline cytology and DNA status.

First published: 21/02/2017

Last updated: 01/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS17902

Study ID

31689

DARWIN EU® study

No

Study countries

Belgium

Study description

This analysis is performed following the outcome of discussion in the HPV Safety Review Team about the potential imbalance observed in the incidence of Cervical Intraepithelial Neoplasms (CIN)2+ and CIN3+ in HPV-015 study: more CIN2+ cases were accrued in the vaccine group in subjects with high grade cytology and who were DNA positive at baseline (before vaccination). This was noticed while preparing a response to questions received by EMA on the submission for HPV-015 study and was decided to investigate further by looking to other efficacy studies including younger subjects (<25 years) and pooled.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicolas Folschweiller

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/01/2017

Study start date

Actual: 31/01/2017

Date of final study report

Actual: 30/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK Vaccines

Study protocol

gsk-207644-sap-redact.pdf (405.36 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Safety Pooling

Data collection methods:

Secondary use of data

Main study objective:

- Provide a summary table on incidence of cases of CIN2, CIN2+, CIN3+ in each group and study, according to baseline status. - Cumulative incidence of CIN2, CIN2+ and CIN3+ will be presented in the form of a graph. - Type distribution for CIN2, CIN2+ and CIN3+ cases will be provided overall and by cytology status at baseline (Normal/Low/High).

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Medicinal product name

CERVARIX

Medicinal product name, other

Havrix

Medical condition to be studied

Human papilloma virus test

Population studied

Short description of the study population

Female subjects with high grade cytology and who were DNA positive at baseline (before vaccination).

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

1

Study design details

Outcomes

- Demographic characteristics presented by pooled studies. - Baseline cytology and DNA status. - Baseline cytology and DNA status by HPV serostatus. - Summary on incidence of CIN2, CIN2+, CIN3+ cases, in each group and study. - Cumulative incidence of CIN2, CIN2+ and CIN3+. - Type distribution for CIN2, CIN2+ and CIN3+ cases: overall and by baseline cytology status.

Data analysis plan

All analysis will be descriptive in nature with the intent to understand the difference in incidence of CIN cases. Interpretation from this analysis needs to be made carefully by considering that this is a post-hoc analysis and no formal sample size computations were done for evaluation of the study objectives. Subjects enrolled in the Clinical studies in this analysis were not randomised for DNA status and cytology status at baseline.

Documents

Study results

gsk-207644-sar-redact.pdf (3.97 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)

Other

Data sources (types), other

Study results

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