205639 - Meta-analysis of the risk of autoimmune thyroiditis diseases, Guillain-Barré Syndrome, and Inflammatory Bowel Disease with Cervarix Vaccination

First published: 29/04/2016

Last updated: 01/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13332

Study ID

31659

DARWIN EU® study

No

Study countries

Belgium

Study description

The purpose of this study is to evaluate the risk of autoimmune thyroiditis diseases, Guillain-Barré Syndrome, and Inflammatory Bowel Disease after Cervarix Vaccination.The study will evaluate the risk of autoimmune thyroiditis diseases, Guillain-Barré Syndrome, and Inflammatory Bowel Disease after Cervarix Vaccination in females.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

Call Center EU Clinical Trials
Vx.publicdisclosureglobal@gsk.com

Study contact

Vx.publicdisclosureglobal@gsk.com

Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 22/04/2016

Study start date
Actual: 22/04/2016

Date of final study report
Actual: 01/09/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK Biologicals

Study protocol

gsk-205639-sap-redact.pdf (1.41 MB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

This study will estimate the overall risk of developing three autoimmune diseases (autoimmune thyroiditis, Guillain Barre Syndrome and Inflammatory

Bowel diseases) following Cervarix vaccination in females.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BM02) papillomavirus (human types 16, 18)

papillomavirus (human types 16, 18)

Medical condition to be studied

Autoimmune thyroiditis

Guillain-Barre syndrome

Inflammatory bowel disease

Population studied

Short description of the study population

Female subjects aged 9 years and above who had received Cervarix Vaccine.

Age groups

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

Estimated number of subjects

Study design details

Outcomes

Occurrence of cases of autoimmune thyroiditis, Guillain-Barré Syndrome, and Inflammatory Bowel Disease during 2 years after the first dose of Cervarix.

Data analysis plan

Meta-analysis method with continuity correction. A continuity correction will be applied to all studies to overcome the single- and double- zero issue. Various continuity corrections have been proposed: constant continuity correction k (for example k=0.5 is commonly used in many software's), continuity correction reciprocal of the opposite treatment arm size, empirical continuity correction.Advantage of this method is that all studies can be included, and any metaanalysis calculation method (inverse variance-weighted method, Peto's method, Mantel-Haenszel's method, etc.) can be applied, all individual studies can also be depicted in forest plots, and heterogeneity among studies can be estimated and tested.

Documents

Study results

gsk-205639-clinical-study-report-redact.pdf (7.54 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)

Clinical Practice Research Datalink

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

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