# 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)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

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)

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**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.

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**Age groups**

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

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**Estimated number of subjects**

1

## 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.

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**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)

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# 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