Study of Cervarix & Idiopathic Thrombocytopenic Purpura using the PGRx information system

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Study Finalised

Administrative details

EU PAS number

EUPAS8093

Study ID

31680

DARWIN EU® study

No

Study countries

☐ France

Study description

This study aims to assess whether the use of Cervarix® is associated with a modified risk of central demyelination, type 1 diabetes (DT1), Cutaneous Lupus, inflammatory arthritis, idiopathic thrombocytopenic purpura (ITP), Lupus erythematosus, myositis and dermatomyositis, Guillain-Barre syndrome and/or Autoimmune thyroiditis and Graves disease by using the PGRx information system.PGRx is an information system that intends to bridge the resource gap to assess the effect of a drug on the risk of adverse events that are infrequent and/or with a long delay of onset. It uses some characteristics of the ad hoc case-control or case-referent design, transposed on a prospective, on-going, population-based recruitment plan. This particular design is called here systematic case-referent design in contrast to the ad hoc case-control or case-referent methodology. The PGRx information system is based on the routine and targeted recruitment of cases of a series of pathologies, compared to population-based referents for the study of exposure to a wide variety of drugs. Drug exposure ascertainment is obtained from two different sources in the PGRx system:A) A structured patient interview (telephone-administered questionnaire)B) The medical data form with the computerized medical prescriptions (interview guide)

Study status

Finalised

Research institutions and networks

Institutions

Real World Studies, LA-SER Research

France

United Kingdom

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Institution | Other | ENCePP partner

Contact details

Study institution contact

Call Center EU Clinical Trials

GSKClinicalSupportHD@gsk.com

Study contact

GSKClinicalSupportHD@gsk.com

Primary lead investigator

Lamiae Grimaldi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/08/2008

Study start date

Actual: 01/08/2008

Date of final study report

Actual: 21/01/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-112677-protocol-part2-redact.pdf(1.55 MB)

gsk-112677-protocol-part1-redact.pdf(1.77 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

This study aims to assess whether the use of Cervarix® is associated with a modified risk of central demyelination, type 1 diabetes (DT1), Cutaneous Lupus, inflammatory arthritis, idiopathic thrombocytopenic purpura (ITP), systemic lupus erythematosus, myositis and dermatomyositis, Guillain-Barre syndrome and/or Autoimmune thyroiditis and Graves disease by using the PGRx information system.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN

HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN

Medical condition to be studied

Demyelination

Type 1 diabetes mellitus

Cutaneous lupus erythematosus

Arthritis infective

Immune thrombocytopenia

Systemic lupus erythematosus

Autoimmune thyroiditis

Dermatomyositis

Guillain-Barre syndrome

Myositis

Population studied

Short description of the study population

Study subjects were cases and referents from the PGRx system satisfying with the following criteria:

1. Female gender
2. Age 14 to 26 years old
3. Patient residing in France (continental)
4. Patient accepting to participate in the study

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

2945

Study design details

Outcomes

To assess whether the use of Cervarix® is associated with a modified risk of central demyelination, type 1 diabetes, cutaneous Lupus, inflammatory arthritis, idiopathic thrombocytopenic purpura, systemic lupus erythematosus, myositis, dermatomyositis, Guillain-Barre syndrome, autoimmune thyroiditis and/or Graves disease at 36 months after the first index case included in the PGRx system.

Data analysis plan

Mainly, two types of analyses are performed with the case-referent design. One without a priori hypothesis the crude analysis (CA) and the other with specific a priori hypotheses the in-depth analysis (IA). The CA is a comparison between cases and referents for their exposure to therapeutic product. The association between an exposure and the occurrence of an adverse event (AE) is quantified through a crude odds ratio (COR) with 90% CI. The COR is not adjusted for the various risk factors (RFs) and not subjected to particular risk curve modelling. In the case of IA, a specific hypothesis is specified and tested regarding an AE and exposure to a specific drug or therapeutic class. This analysis is performed using multivariate techniques with all RFs for a specific pathology as well as co-medications. The association between drug and occurrence of an AE is quantified through adjusted OR with 95% CI. Sensitivity analysis can be performed to assess the robustness of the results.

Documents

Study results

gsk-112677-Clinical-Study-Report_1-redact.pdf(1.61 MB)

gsk-112677-Clinical-Study-Report_2-redact.pdf(1.74 MB)

Study report

gsk-112677-clinical-study-report-redact.pdf(4.5 MB)

gsk-112677-Clinical-Study-Report_3-redact.pdf(1.37 MB)

Study, other information

gsk-112677-Clinical-Study-Report_3-redact.pdf(1.37 MB)

Study publications

Grimaldi-Bensouda L, Rossignol M, Koné-Paut I, Krivitzky A, Lebrun-Frenay C, Cl…

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), other

PGRx Information System France

Data sources (types)

Disease registry

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