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

First published: 27/01/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/31680

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

First published: 23/03/2012

Last updated: 23/03/2012

Institution | Other | ENCePP partner

Contact details

Study institution contact

Call Center EU Clinical Trials

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

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