116602 - Risk of Solid Organ Transplant Rejection Following Vaccination With Pandemrix in the United Kingdom

First published: 27/03/2014

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5975

Study ID

31677

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Solid organ transplant recipients are a recommended priority group for influenza vaccination due to the increased risk of complications associated with influenza infection. Data on the safety of pandemic H1N1 vaccination in transplanted patients is limited, to date, although some studies showed transient increases in alloreactivity, there is no evidence that H1N1 pandemic influenza vaccines caused clinical rejection. In addition, influenza infection is a known independent risk factor for SOT rejection.Considering that transplant recipients are a target risk group for immunisation with future pandemic vaccines, it is important to investigate the risk of rejection following vaccination in this patient population.The study aimed at investigating the risk of rejection (liver, kidney, lung, heart, pancreas) following vaccination with Pandemrix in the UK Clinical Practice Research Datalink GP Online Database (CPRD GOLD) and the linked Hospital Episodes Statistics (HES) database. Analyses were conducted using the self-controlled case series (SCCS) method for perturbed post-event exposure. The potential confounding effect of time since transplantation, seasonal influenza vaccination and other covariates including previous rejections, infections, and malignancies were also to be explored provided information was available. The risk periods were 30 and 60 days after any vaccine dose. The endpoints for the primary and secondary objectives related to the occurrence of SOT rejection after Pandemrix vaccination within the period from 01 October 2009 to 31 October 2010 are presented below and are detailed in the study report.The study also explored the risk of SOT rejection within one and two months after seasonal influenza vaccination, during influenza seasons 2006/2007, 2007/2008 and 2008/2009, results for this tertiary objective will be reported in an annex report.

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

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Study contact

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Primary lead investigator

Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/09/2012

Study start date

Actual: 23/10/2012

Data analysis start date
Actual: 07/08/2013

Date of final study report
Actual: 12/12/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline Biologicals

Study protocol

116602-Protocol-redact.pdf (1.7 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:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess the risk of SOT rejection (liver, kidney, lung, heart, pancreas) within one month after vaccination with Pandemrix.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Medicinal product name

PANDEMRIX

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

INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

Medical condition to be studied

Liver transplant rejection

Kidney transplant rejection

Lung transplant rejection

Heart transplant rejection

Pancreas transplant rejection

Population studied

Short description of the study population

Subjects in the CPRD GOLD and/or HES who had experienced a solid organ transplant (SOT) rejection between 01 September 2006 and 31 October 2010.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

587

Study design details

Outcomes

Occurrence of solid organ transplant rejection (liver, kidney, lung, heart, pancreas) within one month after vaccination with Pandemrix (from 01 October 2009 to 31 October 2010).Medical records extracted from CPRD GOLD and HES, and additional data obtained from complementary information provided by the GPs using a standardised questionnaire. Occurrence of solid organ transplant rejection (liver, kidney, lung, heart, pancreas) within two months after vaccination with Pandemrix (from 01 October 2009 to 31 October 2010).Medical records extracted from CPRD GOLD and HES, and additional data obtained from complementary information provided by the GPs using a standardised questionnaire.

Data analysis plan

The association between SOT rejection and influenza vaccination (Pandemrix or seasonal influenza vaccination) was assessed by calculating the relative incidence (RI), being the ratio of the incidence rate of SOT rejection during the risk period to the incidence rate during the control period, with associated 95% confidence intervals (CI).Primary analyses for the primary objective include:- Number of rejections and person-time in each risk and control period associated with Pandemrix vaccination: control before vaccination, risk after dose1, control after dose1, risk after dose2, control after dose2, etc.- RI estimates associated with Pandemrix vaccination (all doses pooled) adjusted for time since transplantation.- RI estimates associated with Pandemrix vaccination adjusted for time since transplantation and seasonal influenza vaccination.- RI estimates associated with Pandemrix vaccination adjusted for time since transplantation

and each covariate in separate models.

Documents

Study results

116602-clinical-study-report-redact-V1_redacted.pdf (1.92 MB)

Study report

116602-clinical-study-report-annex-redact.pdf (1.95 MB)

Study publications

Dos Santos G, Seifert HA, Bauchau V, Shinde V, Barbeau DM, Cohet C. Adjuvanted …

Cohet C, Haguinet F, Dos Santos G, Webb D, Logie J, Ferreira GL, Rosillon D, Sh…

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

Clinical Practice Research Datalink GP Online Database (CPRD GOLD) United Kingdom, Hospital Episodes Statistics (HES) United Kingdom

Data sources (types)

Other

Data sources (types), other

CPRD-GOLD: Computerised database of linked anonymised longitudinal medical records from primary care.HES: HES has details of all NHS inpatient treatment, outpatient appointments and A&E attendances in England.

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