Privigen® use and haemolytic anaemia in adults and children and the Privigen® safety profile in children with CIDP - an observational hospital-based cohort study in the US (Privigen PASS)

First published: 12/03/2014

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Study Ongoing

Administrative details

EU PAS number

EUPAS6040

Study ID

29795

DARWIN EU® study

No

Study countries

United States

Study description

This study is a 2-part retrospective and prospective hospital-based observational cohort study with objectives to:1. Estimate the incidence of haemolytic anemia (HA), in adults and children, before and after implementation of risk minimization measures in the process of screening of plasma donors and in the manufacturing process of Privigen®.2. Evaluate the safety profile of Privigen® in children (0-18 years) with chronic inflammatory demyelinating polyneuropathy (CIDP).Part 1 of the study will compare results from three separate calendar-time periods (Jan 2008 to Dec 2012, Oct 2013 to Dec 2015 and Oct 2016 to Apr 2019) to assess the effect of the risk minimization measures. Part 2 will analyse data accumulated over the whole study period to assess the adverse event (AE) profile in children with CIDP.The data source is the Premier Perspective™ database in the United States.Study Population: Adult and paediatric patients with at least one dispensing for Privigen® in US hospitals contributing to the Premier Perspective™ database. As of the writing of the first and second interim reports for this study, the Premier database contained data on 8,993 and 7,710 adult and paediatric patients administered Privigen between 1 January 2008 and 31 December 2012 (Period 1: baseline) and between 1 October 2013 and 31 December 2015 (Period 2) respectively.Seventeen patients aged <18 were treated with Privigen® for CIDP between 1 January 2008 and 31 December 2015 . Variables: The exposure of interest is Privigen®. The outcome in both adults and children in Part 1 of the study is the incidence of HA. The outcome variables to be assessed in children with CIDP in Part 2 of the study include diagnosis codes for aseptic meningitis, acute renal failure, thromboembolic events and anaphylactic reactions

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Study status

Ongoing

Research institutions and networks

Institutions

Institute for Epidemiology, Statistics and Informatics

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Carlos Martinez

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2014

Actual: 31/10/2014

Study start date

Planned: 25/02/2014

Actual: 07/04/2014

Data analysis start date
Planned: 07/04/2014

Actual: 07/04/2014

Date of interim report, if expected
Planned: 15/10/2014

Actual: 03/11/2014

Date of final study report
Planned: 01/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CSL Behring

Study protocol

CSL_Privigen_PASS_Protocol_Final.pdf (733.16 KB)

CSL_Privigen_PASS_Protocol_V2_ Final.pdf (1.6 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

IgPro10_5003

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Risk assessment of known and potential risks with use of Privigen®

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Chronic inflammatory demyelinating polyradiculoneuropathy

Demyelinating polyneuropathy

Primary immunodeficiency syndrome

Congenital hypogammaglobulinaemia

Guillain-Barre syndrome

Kawasaki's disease

Secondary immunodeficiency

Population studied

Age groups

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

Special population of interest

Immunocompromised

Estimated number of subjects

25.000

Study design details

Outcomes

Incidence of haemolytic anemia, occurrence of aseptic meningitis, acute renal failure, thromboembolic events and anaphylactic reactions in pediatric patients with CIDP

Data analysis plan

For Part 1 results will include descriptive statistics of the standardized incidence of first-time occurrence of HA during the different calendar-time periods. Cox Proportional hazards modelling will be used to compare the hazard rate of the first-time occurrence of HA following the implementation of each of the two risk minimisation measures to the baseline hazard of HA (before the measures were introduced). For Part 2 results will include the incidence rates of AEs for the paediatric population with CIDP during the cumulative study period.

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

Premier PerspectiveTM database United States

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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