Postmarketing Requirement (PMR) Non-Interventional 2-armed Study to Evaluate the Safety of octagam® Immune Globulin Intravenous (Human) 5% Liquid Preparation, with a Special Emphasis on Monitoring, Analysis and Reporting of Thromboembolic Events (TEEs) (GAM5-28)

First published: 20/08/2015

Last updated: 20/08/2015

Study Ongoing

Administrative details

EU PAS number

EUPAS10738

Study ID

10739

DARWIN EU® study

No

Study countries

United States

Study description

This observational study compares the incidence of TEEs in PID patients who receive regularly prescribed IVIG all 3 to 4 weeks in two groups: Octagam 5% vs. other brands.

Study status

Ongoing

Research institutions and networks

Institutions

Octapharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Svorc Daniel daniel.svorc@octapharma.com

Study contact

daniel.svorc@octapharma.com

Primary lead investigator

Svorc Daniel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/04/2011

Actual: 29/04/2011

Study start date

Actual: 01/05/2013

Date of final study report

Planned: 29/05/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Octapharma

Study protocol

090-NISP-GAM5-28-v08_06-Aug-2015.pdf (871.1 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To assess and evaluate the safety profile of octagam 5% under routine clinical use, with a special emphasis on the occurrence of TEEs. The incidence of TEEs in patients receiving octagam 5% will be compared with the incidence rate in a matching concurrent control group of patients receiving other IVIGs for routine clinical use.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J06BA02) immunoglobulins, normal human, for intravascular adm.

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Medical condition to be studied

Primary immunodeficiency syndrome

Population studied

Age groups

- 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

500

Study design details

Outcomes

Thromboembolic event (TEE), Adverse drug reactions

Data analysis plan

The primary objective of this study is the close monitoring of the occurrence of TEEs. This statistical monitoring will be carried out by means of the Maximized Sequential Probability Ratio TEST (MaxSPRT) for Binomial data, cf. Kulldorff et. al. 2011

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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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