Post-Authorisation Safety Study (PASS) of CLAIRYG® (Human normal immunoglobulin for intravenous use) in children under 12 years treated for primary immunodeficiency (PID) or immune thrombocytopenic purpura (ITP) (IGNGPASSP)

First published: 22/05/2020

Last updated: 23/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/33321

EU PAS number
EUPAS33320

Study ID
33321

DARWIN EU® study
No

Study countries
France

Study description
The primary objective is to evaluate the safety of CLAIRYG® administered as part of common practice in children under 12 years treated for PIDs or ITP over a follow-up period of 12 months. The secondary objectives are as follows: - To describe the conditions of use

of CLAIRYG® as part of common practice in children under 12 years, - And to collect efficacy data to better document the benefit/risk ratio in the two pathologies studied: PIDs and ITP.

Study status
Finalised

Research institution and networks

Institutions

LFB - Paris-Saclay
First published: 01/02/2024
Last updated 01/02/2024
Institution

Bordeaux University Hospital (CHU de Bordeaux)
France
First published: 01/02/2024
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Institution
Hospital/Clinic/Other health care facility

Necker Hospital PARIS, University Hospital ROUEN, Pellegrin Hospital BORDEAUX, Jeanne de Flandre Hospital LILLE, University Hospital ANGERS, Brabois Hospital NANCY

Contact details

Study institution contact
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Primary lead investigator
Jean_Louis STEPHAN
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
15/07/2014

Study start date
Actual:
26/10/2015

Date of interim report, if expected
Actual:
17/12/2020

Date of final study report
Actual:
02/02/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

LFB

Study protocol

Protocole_ClairYg_ final_V 3 0_2015_01_27 (EN) anonymisé.pdf(2.41 MB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Main study objective:
The main objective of the study is to evaluate the safety of CLAIRYG® in common practice as replacement therapy for PIDs in children under 12 years, over a period of 12 months. The children with ITP treated at the same sites as the children with PIDs will also be included in the study in order to collected safety data in children receiving higher doses for immunomodulatory treatment.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Observational study

Study drug and medical condition

Name of medicine, other
CLAIRYG

Medical condition to be studied
Primary immunodeficiency syndrome
Immune thrombocytopenia

Population studied

Age groups
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)
Children (2 to < 12 years)

Estimated number of subjects
59

Study design details

Outcomes
This study will collect all serious and non-serious adverse events, whether or not they are related to the administration of CLAIRYG® occurring in the children, with PID or ITP, treated with CLAIRYG® during the period of their follow-up, in order to document the product's safety in real conditions of use. To describe the conditions of use of Clairyg as part of common practice. To collect efficacy data to better document the benefit/risk ratio in the 2 diseases studies (PIDs and ITP) in children Under 12 years.

Data analysis plan
For each group, a descriptive analysis will be performed on all of the data collected. - Quantitative variables will be described by their number, mean, standard deviation, median, limit values and missing data. - Qualitative variables will be described by their number, percentage and missing data. The 95% bilateral confidence intervals will only be given where applicable. Safety analysis : AE will be coded using the MedDRA dictionary classification. The number and frequency of AE will be described and listed by System Organ Class (SOC), Lowest Level Term (LLT) and Preferred Terms (PT). All AE will be described by type, seriousness, intensity/severity, causality, outcome. Exposure to CLAIRYG: mean doses (g and g/kg) administered per infusion (PID) or per treatment session (ITP) will be analysed. Efficacy analysis on each group : - PID: analysis of infections and IgG through serum levels - ITP: analysis of bleedings and platelet counts

Documents

Study results
PASS-CLAIRYG - Results summary_V1.0_17102023.pdf(397.1 KB)

Data management

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