Eptacog beta post marketing safety surveillance using aggregated data reports from the EUHASS Registry (F7TG2206-EUHASS Registry)

First published: 05/06/2023

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS105020

Study ID

105021

DARWIN EU® study

No

Study countries

Austria

Belgium

France

Germany

Italy

Netherlands

Spain

United Kingdom

Study description

This Post Marketing safety Surveillance study is based on observational data collection from the European Hemophilia Safety Surveillance (EUHASS) cohort. EUHASS is a pharmacovigilance program to monitor the safety of treatments for people with inherited bleeding disorders in maintaining a database of all the haemophilia centres in Europe. EUHASS will transmit to the sponsor, LFB Biotechnologies 4 reports of adverse events issued at the end of each 3 month period and a detailed annual report.

Study status

Ongoing

Research institutions and networks

Institutions

European Haemophilia Safety Surveillance System (EUHASS)

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Institution

2 sites Austria, 2 sites Belgium, 6 sites France, 7 sites Germany, 10 sites Italy, 4 sites Netherlands, 5 sites Spain, 21 sites United Kingdom

Contact details

Study institution contact

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Study contact

barthez@lfb.fr

Primary lead investigator

Emmanuelle LAGRUE

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/01/2023

Study start date

Actual: 25/01/2023

Date of final study report

Planned: 30/06/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

LFB Biotechnologies

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 type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective will be to determine the number and incidence of important potential risks defined as: - Hypersensitivity reactions -

Thromboembolic events, including those due to drug-drug interactions with activated or nonactivated prothrombin complex or other haemostatic agents - Immunogenicity

Study drug and medical condition

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

EPTACOG BETA (ACTIVATED)

Medical condition to be studied

Factor VIII deficiency

Factor IX deficiency

Additional medical condition(s)

with inhibitors

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

168

Study design details

Outcomes

- Number of allergic or other acute event and thromboses - Incidence of allergic or other acute event and thromboses - Incidence of antidrug antibodies

Data analysis plan

Data management including data collection is under the responsibility of the EUHASS registry, in accordance with the current version of the EUHASS working protocol. At the end of each 3-month period, participating centres have 3 weeks to report their data, so the three-monthly report can be produced within four weeks of the end of each surveillance period. Every 12 months, a more detailed analysis is provided. The number and incidence of subjects with treatment-emergent AEs (TEAEs), specifically allergic or other acute events, thrombosis will be assessed and presented in a final report.

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

EUHASS - Blood disorders

Data sources (types)

Other

Data sources (types), other

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