A Low-Interventional Multicentre Post-Authorisation Safety Study for Voncento / Biostate / Aleviate for Routine Prophylaxis, Treatment of Bleeding Events and / or Surgery in Male Subjects with Haemophilia A (Biostate_4001)

First published: 10/07/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS19806

Study ID

34657

DARWIN EU® study

No

Study countries

Germany

Hong Kong

Study description

This is a multicentre, open-label, single-arm, phase 4, low-interventional PASS study. It is planned to evaluate the combined safety data from this post-marketing study during a 5-year accrual period, and from disease registries (EUHASS) to reach a target of approximately 100 patients. This is a prospective study in subjects with haemophilia A to investigate the safety of Voncento as used for the treatment of acute bleeding episodes, routine prophylaxis, and / or perioperative bleeding in these subjects. Eligible subjects will have haemophilia A and be known to have been exposed to FVIII-containing products for at least 150 exposure days. Enrolled subjects will be treated with Voncento at participating study centres at the discretion of the PI according to current local practice, and will be followed for approximately 100 EDs.This study was never activated and no subjects were enrolled.

Study status

Finalised

Research institutions and networks

Institutions

CSL Behring

Moerfelden-Walldorf HZRM Moerfelden-Walldorf, Germany, Princess Margaret Hospital Hong Kong

Contact details

Study institution contact

Clinical Trial Registration Coordinator
clinicaltrials@cslbehring.com

Study contact

clinicaltrials@cslbehring.com

Primary lead investigator

Clinical Trial Registration Coordinator

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/08/2016

Actual: 15/08/2016

Study start date

Planned: 03/02/2020

Actual: 31/03/2020

Date of final study report

Planned: 21/07/2023

Actual: 31/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CSL Behring

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To investigate the immunogenicity of Voncento in Previously Treated Patients (PTPs) with haemophilia A.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Low interventional, Post-Authorisation Safety Study

Study drug and medical condition

Medicinal product name

VONCENTO

Medicinal product name, other

Biostate, Aleviate

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

HUMAN COAGULATION FACTOR VIII

Anatomical Therapeutic Chemical (ATC) code

(B02BD06) von Willebrand factor and coagulation factor VIII in combination
von Willebrand factor and coagulation factor VIII in combination

Medical condition to be studied

Factor VIII deficiency

Population studied

Short description of the study population

Subjects with haemophilia A who have been treated with Voncento for the treatment of acute bleeding episodes, routine prophylaxis, and / or perioperative bleeding.

Age groups

- 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

Other

Special population of interest, other

Hemophilia A patients

Estimated number of subjects

100

Study design details

Outcomes

The incidence of FVIII inhibitor development, Nature and incidence of reported adverse events, serious adverse events, and adverse events of special interest, and lack of effect (ie, a less than expected response to Voncento treatment when given for a bleeding event) as assessed by the investigator.

Data analysis plan

All analyses will be performed for the Safety Population, which will comprise all enrolled subjects who received at least 1 dose of Voncento after signed consent to participate in the study. Study endpoints will be summarised by descriptive statistics. Continuous variables will be summarised in terms of the mean, standard deviation, median, minimum, and maximum. Other descriptive statistics (eg, quartiles, coefficients of variation) may be reported when appropriate. Categorical variables will be summarised using frequency counts and percentages. Confidence intervals will be calculated for key parameters or estimates as warranted.

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)

Disease registry

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

Unknown