

# 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

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS19806

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### Study ID

34657

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### DARWIN EU® study

No

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### Study countries

 Germany

 Hong Kong

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### **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.

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### **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@cslobehring.com

Study contact

[clinicaltrials@cslobehring.com](mailto:clinicaltrials@cslobehring.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

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### Study start date

Planned: 03/02/2020

Actual: 31/03/2020

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### 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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

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

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Low interventional, Post-Authorisation Safety Study

## Study drug and medical condition

**Medicinal product name**

VONCENTO

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**Medicinal product name, other**

Biostate, Aleviate

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

HUMAN COAGULATION FACTOR VIII

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**Anatomical Therapeutic Chemical (ATC) code**

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

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**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.

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**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)
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## **Special population of interest**

Other

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## **Special population of interest, other**

Hemophilia A patients

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## **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.

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## **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

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### **Data sources (types)**

[Disease registry](#)

[Other](#)

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### **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

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### **Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown