

Multicenter non-interventional post-authorization safety study (NI-PASS) to monitor the incidence of relevant and expected rare adverse events including lack of efficacy among CKD patients receiving s.c. Binocrit® or Epoetin alfa HEXAL®

**First published:** 30/12/2016

**Last updated:** 28/04/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS14525

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### Study ID

49342

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### DARWIN EU® study

No

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### Study countries

-  Bulgaria
  -  Croatia
  -  Germany
  -  Greece
  -  Italy
  -  Poland
  -  Romania
  -  Slovakia
  -  Slovenia
  -  Spain
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### **Study description**

This is a non-interventional study to address the post-authorization requirement to evaluate the safety profile of Binocrit® and Epoetin alfa HEXAL® administered sub-cutaneously (s.c.) in patients with chronic kidney disease (CKD)-induced anemia under real life conditions. The purpose of this non-interventional Post-Authorization Safety Study is to increase dataset on the safe use of the product by extending the safety database of patients with CKD-induced anemia who receive s.c. Binocrit® or Epoetin alfa HEXAL® treatment and by monitoring closely the adverse event profile under real-life post-approval conditions.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

## Sandoz

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

129 centres involved in the study

## Contact details

### Study institution contact

Sandoz Clinical Disclosure Officer  
sandoz.disclosure@sandoz.com

Study contact

[sandoz.disclosure@sandoz.com](mailto:sandoz.disclosure@sandoz.com)

### Primary lead investigator

Sandoz Clinical Disclosure Office

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 25/10/2016

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**Study start date**

Planned: 31/03/2017

Actual: 12/04/2017

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**Data analysis start date**

Planned: 07/02/2023

Actual: 08/02/2023

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**Date of final study report**

Planned: 17/11/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Hexal AG

## 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)

## Other study registration identification numbers and links

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

The primary objective of this study is to assess the incidence of relevant and expected rare Adverse Events (defined as Adverse Events of Special Interest) in response to Binocrit® or Epoetin alfa HEXAL® s.c. treatment in patients with CKD-induced anemia.

### Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Prospective Observational Study

### Study drug and medical condition

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

EPOETIN ALFA

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### **Medical condition to be studied**

Chronic kidney disease

Nephrogenic anaemia

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

Renal impaired

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### **Estimated number of subjects**

2500

## Study design details

### **Outcomes**

The primary endpoint will be the incidence of Adverse Events (AEs) of Special Interest (including Pure Red Cell Aplasia and Lack of Efficacy). AEs of Special Interest are defined in the safety section of the protocol. Incidence of serious

AEs, incidence of AEs, number of patients discontinuing the study prematurely and reasons for discontinuations, red blood hematology parameters over time (hemoglobin concentration, red blood cells (RBC), absolute and relative reticulocyte counts, hematocrit), number of patients receiving transfusions (whole blood and/or packed RBC), weekly epoetin dosage over time

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### **Data analysis plan**

Due to the nature of the study, only descriptive statistical methods will be applied. AE incidences will be presented as percentages of patients with the corresponding exact 95% Clopper-Pearson confidence intervals, as well as incidence rates based on duration at risk.

## Documents

### **Study report**

[CHX575-507 Study Report Body\\_FinalForEUPAS.pdf](#) (1.42 MB)

## 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

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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**

No