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

Study ID

49342

DARWIN EU® study

No

Study countries

- [ ] Bulgaria
- [ ] Croatia
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Poland
- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain

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.

Study status

Ongoing

Research institutions and networks

Institutions

Sandoz

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Institution

129 centres involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sandoz Clinical Disclosure Office

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/10/2016

Study start date
Planned: 31/03/2017

Actual: 12/04/2017

Data analysis start date
Planned: 07/02/2023

Actual: 08/02/2023

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

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

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

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

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)

Special population of interest

Renal impaired

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

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