

# Post-Authorisation Safety Cohort Observation of Retacrit™ (epoetin zeta) Administered Subcutaneously for the Treatment of Renal Anaemia (PASCO II) (PASCOII)

**First published:** 09/07/2013

**Last updated:** 22/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS4276

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### Study ID

41085

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### DARWIN EU® study








No

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### Study countries

 Bulgaria

 Croatia

-  Denmark
  -  Finland
  -  France
  -  Germany
  -  Greece
  -  Ireland
  -  Italy
  -  Portugal
  -  Spain
  -  Sweden
  -  United Kingdom
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### **Study description**

PASCOII is a non-interventional PASS study initiated by the MAH Hospira as part of the RMP. The primary objective of the study is to estimate the incidence of pure red cell aplasia, neutralising antibodies, lack of efficacy and thromboembolic events in renal anaemia. The secondary objective is to obtain information on adverse drug reactions, use of epoetin zeta during pregnancy and lactation and data on long term use.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Multiple centres: 198 centres are involved in the study

## Contact details

### Study institution contact

Stephanie Salts [Stephanie.Salts@Pfizer.com](mailto:Stephanie.Salts@Pfizer.com)

Study contact

[Stephanie.Salts@Pfizer.com](mailto:Stephanie.Salts@Pfizer.com)

### Primary lead investigator

Stephanie Salts

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 25/05/2010

Actual: 25/05/2010

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### Study start date

Planned: 07/07/2010

Actual: 07/07/2010

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### Data analysis start date

Actual: 02/06/2020

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### Date of final study report

Planned: 12/10/2022

Actual: 06/11/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Hospira UK Limited (a Pfizer Company)

## Study protocol

[PASCO II Protocol Version 4.0\\_20 March 2015\\_Signed.pdf](#) (550.3 KB)

[C1111006 Protocol Amendment 4 \(clean\) 02 August 2019.pdf](#) (1.75 MB)

## 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:**

Human medicinal product

Disease /health condition

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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

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The main objective is to estimate the incidence of Pure Red Cell Aplasia (PRCA), neutralising antibodies, lack of efficacy, and thromboembolic events under treatment with Retacrit (epoetin zeta) administered sub cutaneously in patients with renal anaemia.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Non-interventional, longitudinal, multi-centre, defined population, prospective observation

## Study drug and medical condition

## **Medicinal product name**

RETACRIT

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## **Medical condition to be studied**

Aplasia pure red cell

Renal failure

## **Population studied**

### **Short description of the study population**

Patients are eligible for enrolment if the following applies:

1. Patients treated SC with Retacrit (epoetin zeta) for renal anaemia.
2. Informed consent given in writing after being provided with detailed information about the characteristics of this observation by the physician.
3. Patients expected to be available for 3 years of observation

Patients are not eligible for enrolment if the following applies:

1. Any contraindication as per the current SmPC of Retacrit
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### **Age groups**

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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### **Estimated number of subjects**

6700

## Study design details

### **Outcomes**

Thromboembolic events including cerebrovascular events (e.g. cerebrovascular accident, cerebral infarction, cerebral haemorrhage, transient ischaemic attack), deep vein thrombosis, myocardial infarction and pulmonary embolism. Descriptive evaluation including incidence rates of adverse drug reactions (ADRs). Information on treatment with Retacrit (epoetin zeta) during pregnancy and lactation, and long term use.

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### **Data analysis plan**

The incidence rate of adverse events of special interest will be calculated per patient. The ADRs will be evaluated and described including incidence rates.

## Documents

### **Study results**

[epoe-09-11-abstract.pdf](#) (1.89 MB)

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## Study report

[epoe-09-11-report-body.pdf](#) (8.5 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