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

PURI

https://redirect.ema.europa.eu/resource/41085

EU PAS number

EUPAS4276

Study ID

41085

DARWIN EU® study

No

Study countries

- [ ] Bulgaria
- [ ] Croatia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Italy
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 198 centres are involved in the study

Contact details

Study institution contact

Stephanie Salts

Study contact

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

Study start date

Planned: 07/07/2010

Actual: 07/07/2010

Data analysis start date

Actual: 02/06/2020

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

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

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

Non-interventional study design, other

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

Study drug and medical condition

Name of medicine

RETACRIT

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

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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.

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)

Study report

epoe-09-11-report-body.pdf(8.5 MB)

Data management

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