Thromboembolic Risk in Patients with Chronic Kidney Disease Treated receiving Epoetin zeta or other Erythropoietin Stimulating Agents – the BIPS study

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Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10254

Study ID

29008

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Erythropoietin belongs to the group of erythropoiesis-stimulating agents (ESAs) that stimulate the production of red blood cells from the bone marrow. Erythropoietin-containing medicines are used to treat anaemia in patients with cancer who are receiving chemotherapy and in patients with chronic kidney disease (CKD). Currently several medicinal products containing erythropoietin are approved in the European Union including biosimilar products. One of those is epoetin zeta which was licensed 2007 and is marketed in Germany as Silapo®. Several studies showed an increased risk for thromboembolic events associated with ESA use, if ESAs differ with respect to their thromboembolic properties is unknown. To examine the risk of thromboembolic events in patients with CKD treated with ESAs, a retrospective cohort study based on data from the German Pharmacoepidemiological Research database will be conducted for the years 2007 to 2011. The study will compare the risk of thromboembolic events such as myocardial infarction, deep vein thrombosis or pulmonary embolism in patients treated with Epoetin zeta as compared with patients receiving epoetin alpha or other ESAs.

Study status

Finalised

Research institutions and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

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Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Tania Schink

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/07/2011

Actual: 28/07/2011

Study start date

Planned: 01/01/2007

Actual: 01/01/2007

Date of final study report

Planned: 31/03/2017

Actual: 10/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

STADA Arzneimittel AG

Study protocol

Report_HDBS_v1.2.pdf(212.01 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to compare the incidence of thromboembolic events in patients with renal anaemia treated with epoetin zeta and patients with renal anaemia treated with epoetin alpha.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Nested case-control study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B03XA01) erythropoietin

erythropoietin

(B03XA02) darbepoetin alfa

darbepoetin alfa

(B03XA03) methoxy polyethylene glycol-epoetin beta

methoxy polyethylene glycol-epoetin beta

Medical condition to be studied

Chronic kidney disease

Population studied

Short description of the study population

Patients with chronic kidney disease (CKD) included in the GePaRD exposed for the first time to epoetin zeta, epoetin alfa or other epoetins available on the market during the study period.

Age groups

Preterm newborn infants (0 – 27 days)

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

Estimated number of subjects

5200

Study design details

Outcomes

The main study endpoint is the composite endpoint of the three thromboembolic events:• Acute myocardial infarction• Deep vein thrombosis and/or pulmonary embolism• Cerebrovascular event i.e. cerebrovascular accident, cerebral infarction, transient ischaemic attack or cerebral haemorrhage. These three events will be analysed separately as secondary outcomes.

Data analysis plan

The risk of thromboembolic events in CKD patients treated with epoetin zeta will be compared to the risk of thromboembolic events in CKD patients treated with epoetin alpha or other epoetins in a case-control analysis. Epoetin users will be identified based on drug prescriptions. Risk assessment in all groups of patients during the study period will be based on hospital or outpatient diagnoses. Information on sex, year of birth, SHI, co-morbidity, and co-medication will be gathered for the study period and for the year before cohort entry. Cases will be defined as current users if they are exposed to any ESA on the index day, as recent users if ESA exposure ends 1-30 days before the index day, and as past users if ESA exposure ends > 30 days before the index day.

Data management

Data sources

Data source(s)

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative healthcare records (e.g., claims)

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

Unknown