Post-authorization safety study with Epoetin theta in patients with chronic kidney disease An observational, non-interventional, multinational, multicentre, uncontrolled, prospective cohort study

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Study Finalised

Administrative details

EU PAS number

EUPAS11237

Study ID

28615

DARWIN EU® study

No

Study countries

Austria

Czechia

Germany

Greece

Study description

The study was conducted to evaluate if therapy with Epoetin theta in patients with Chronic Kidney Disease (CKD) increases the risk for cardiovascular morbidity and Pure Red Cell Aplasia (PRCA). The primary objective of the study was to assess the incidence and severity of predefined cardiovascular events including ischaemic stroke in a large population of 1,000 CKD patients treated with Epoetin theta. The secondary objective was to detect and describe any adverse drug reaction including PRCA. This was a multinational, multicentre, observational, non-interventional, uncontrolled, prospective cohort studyconducted in Austria, the Czech Republic, Germany and Greece during April 2012 -January 2014.

Study status

Finalised

Research institutions and networks

Institutions

PHARMALOG

Multiple centres: 55 centres are involved in the study

Contact details

Study institution contact

Faulhaber Nicola Nicola.Faulhaber@ratiopharm.de

Study contact

Nicola.Faulhaber@ratiopharm.de

Primary lead investigator

Faulhaber Nicola

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/05/2011

Actual: 09/05/2011

Study start date

Planned: 30/04/2012

Actual: 19/04/2012

Date of interim report, if expected

Planned: 30/10/2012

Actual: 30/10/2012

Date of final study report

Planned: 30/10/2014

Actual: 30/10/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merckle GmbH

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:

Primary data collection

Main study objective:

The primary objective of this PASS was to assess the incidence and severity of predefined cardiovascular events including ischaemic stroke in a large population of 1,000 CKD patients treated with Epoetin theta.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

EPOETIN THETA

Medical condition to be studied

Ischaemic stroke

Myocardial infarction

Cardiac failure

Cardiac disorder

Aplasia pure red cell

Population studied

Short description of the study population

Chronic Kidney Disease (CKD) patients treated with Epoetin theta.

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

1.000

Study design details

Outcomes

Incidence and severity of predefined cardiovascular events, including ischaemic stroke, Any additional adverse drug reaction (ADR), including possible risk of PRCA.

Data analysis plan

Due to the non-interventional character of this study, only an exploratory descriptive statistical analysis was performed.Qualitative (i.e. binary, categorical and ordinal) parameters were summarized by means of descriptive statistics, i.e. mean, standard deviation, median, minimum and maximum for continuous variables or frequency tables for categorical variables. The analysis

of safety data was done separately for reportable adverse events (RAE, i.e. predefined cardiovascular events including ischaemic stroke) and for ADRs.RAEs were analyzed using the subterms summarised under the topics “cardiac disorders”, “cardiac failure”, “myocardial infarction”, and “ischaemic stroke”.The incidences of RAEs and ADRs were summarised by severity and frequency. Two-sided 95% Clopper-Pearson CIs were calculated, if appropriate.For patients with RAE, plots of the Hb values (including median and mean values) were provided.

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

Unknown