Risk of Venous Thromboembolism and All-Cause Mortality in Cancer Patients Treated with Epoetins either with or without Transfusions versus Cancer Patients Treated with Transfusions alone

First published: 06/10/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7619

Study ID

29004

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The objective of this study was to assess the risk of venous thromboembolism (VTE) and all-cause mortality in incident cancer patients receiving epoetin treatment either with or without additional transfusions compared to cancer patients receiving blood transfusions alone in Germany in a real world setting for the time period between January 01, 2004 and December 31, 2009.A nested case-control analysis using conditional logistic regression was conducted to estimate adjusted ORs with corresponding 95% CIs for VTE and treatment with epoetin and/or transfusions in two different time windows. Further, multivariable Cox proportional hazard regression models were applied to assess the risk of all-cause mortality comparing patients receiving epoetin treatment to those treated with transfusions. Therefore a respective time-dependent exposure variable was included.

Study status

Finalised

Research institutions and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

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

Actual: 28/02/2012

Study start date

Planned: 01/01/2004

Actual: 01/01/2004

Date of final study report

Actual: 15/11/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

STADA Arzneimittel 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)

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 main objective of this study was to assess the risk of VTE and all-cause mortality in incident cancer patients receiving epoetin treatment either with or without additional transfusions compared to cancer patients receiving blood transfusions alone in Germany in a real world setting.

Study Design

Non-interventional study design

Case-control

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

(B03XA04) peginesatide

peginesatide

Medical condition to be studied

Deep vein thrombosis

Pulmonary embolism

Death

Population studied

Short description of the study population

Cancer patients receiving epoetin treatment either with or without additional transfusions.
Cohort members had to fulfil all of the following inclusion criteria: (i) at least 12 months of continuous insurance time before the initial outpatient epoetin dispensation or transfusion administration, (ii) no outpatient epoetin dispensation or code indicating transfusion administration within the 12 months before cohort entry, and (iii) at least one outpatient or inpatient diagnosis of cancer other than non-melanoma skin cancer or a code indicating chemotherapy within 6 months before cohort entry, but no diagnosis of cancer or code indicating chemotherapy between 6 months and 1 year before cohort entry.

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

Immunocompromised

Estimated number of subjects

69888

Study design details

Outcomes

- Venous thromboembolism (defined as deep vein thrombosis of the leg/hip or pulmonary embolism)- All-cause mortality was defined as death of any cause. Deaths were identified using core and hospital data searching for death as the reason for end of insurance or the reason for the end of hospitalization, respectively.

Data analysis plan

Characteristics of patients at the time of cohort entry and treatment with epoetin and transfusions were described stratified by sex and age at cohort entry, and compared between the five treatment groups (epoetin treatment only, transfusions only, epoetin followed by transfusions, transfusions followed by epoetin, concomitant initiation of transfusions and epoetin).A nested case-control analysis using conditional logistic regression was conducted to estimate adjusted ORs with corresponding 95% CIs for VTE and recent treatment with epoetin and/or transfusion. Treatment was defined as “recent” if a VTE occurred up to 28 days after the end of the respective therapy.Multivariable Cox proportional hazard regression models were used to estimate adjusted HRs and related 95% CIs. The main objective was to compare patients receiving epoetin treatment either with or without additional transfusions compared to cancer patients receiving blood transfusions alone.

Documents

Study results

Abstract_Epoetin.pdf(17.51 KB)

Study publications

Douros A, Jobski K, Kollhorst B, Schink T, Garbe E. Risk of venous thromboembol...

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 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

No