

# 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.

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## 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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## **Primary lead investigator**

Tania Schink

[Primary lead investigator](#)

# Study timelines

## **Date when funding contract was signed**

Actual: 28/02/2012

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## **Study start date**

Planned: 01/01/2004

Actual: 01/01/2004

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## **Date of final study report**

Actual: 15/11/2013

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# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

## 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:**

Disease /health condition

Human medicinal product

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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

##### **Data collection methods:**

### **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

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### **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

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## **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.

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### **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)

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### **Special population of interest**

Immunocompromised

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## **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.

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## **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 \(17.51 KB\)](#)

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## Study publications

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

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## 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

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### 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

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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