

# PRostAte Cancer vTe In SwEden: epidemiology and anticoagulation treatment of VTE (PRACTISE)

**First published:** 27/05/2019

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS29848

### Study ID

44410

### DARWIN EU® study

No

### Study countries

☐ Sweden

### Study status

Finalised

## Research institutions and networks

# Institutions

## Bayer AG

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Bayer Clinical Trials BAYER AG clinical-trials-contact@bayer.com

Study contact

[clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)

### Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 12/05/2019

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### Study start date

Planned: 30/05/2019

Actual: 30/05/2019

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### **Date of final study report**

Planned: 23/09/2021

Actual: 23/08/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

[20653\\_Study Protocol\\_V1.0\\_2019-05-12\\_redacted.pdf](#)(926.18 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **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

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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

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Among all men with PCa: To describe socio-demographic and clinical characteristics at the date of an incident PCa diagnosis. To estimate the occurrence of cancer-related VTE. To describe the cancer therapies in PCa at the initial time after diagnosis. Among men with PCa and a first cancer-related VTE event: To characterize the long-term anticoagulation treatment including choice of drug

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

DABIGATRAN ETEXILATE

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## **Anatomical Therapeutic Chemical (ATC) code**

(B01AF01) rivaroxaban

rivaroxaban

(B01AF02) apixaban

apixaban

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## **Medical condition to be studied**

Prostate cancer

# Population studied

## **Short description of the study population**

The population will be selected from the PCBaSe 4.0 database that contains patients with PCa as well as PCa-free men from the general population in Sweden who have been frequency-matched to incident cases of PCa by birth year and county of residence. A sub-population will include PCa patients with a cancer-related VTE event.

- PCa patients

- Inclusion criteria

Initially all patients newly diagnosed with PCa between 2007-2016 with at least one year before the end of follow up date (31 December 2017) will be included. From this population, a sub-population of PCa patients with a first cancer-related VTE event will be selected.

- Exclusion criteria

No exclusions will be made.

- Men without PCa

- Inclusion criteria

All PCa-free men included in PCBaSe who are randomly selected from the general population of Sweden with the same birth year and county of residence of PCa patients diagnosed between 2007- 2016.

- Exclusion criteria

A PC free men diagnosed with a prostate cancer during the follow up will be identified and censored.

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### **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)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Prostate cancer patients

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### **Estimated number of subjects**

99999

## **Study design details**

## Outcomes

Patients' socio-demographic and clinical characteristics at the date of an incident PCa diagnosis  
Incidence rate of cancer-related VTE  
Cancer therapies in PCa  
Choice of anticoagulant drug and duration of treatment  
Occurrence of recurrent VTE events  
Time between a first cancer-related and a recurrent VTE event  
Incidence rate of post-VTE bleeding event, Among PCa-free men:  
Subject's socio-demographic at the time of inclusion into the database  
Subject's clinical characteristics at the time of inclusion into the database  
Incidence rate of VTE events

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## Data analysis plan

Descriptive statistics will be used to define the socio-demographic and clinical characteristics of all PCa patients and PCa-free men, incidence rate of cancer-related VTE events will be also described by Kaplan-Meier curves in different strata. Anticoagulation treatment received by the PCa patients after the first cancer-related VTE event will be reported by type of anticoagulation (LMWH, VKAs and NOACs) and its estimated duration (up to 3 months, 3-6 months, more than 6 months). Among this sub-group of patients, the occurrence (incidence rates) of recurrent VTE and the time to recurrence, post-VTE bleeding leading to hospitalisation, and mortality will be calculated by the type and duration of AC treatment.

## Documents

### Study results

[20653\\_EU PAS Abstract\\_Redacted\\_V1.0\\_2021-08-23.pdf](#)(350.7 KB)

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### Study report

[20653\\_Study Report\\_Redacted\\_V1.0\\_2021-08-23.pdf](#)(1.48 MB)

## Data management

## Data sources

## **Data sources (types)**

Disease registry

## 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