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

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/05/2019

Study start date

Planned: 30/05/2019

Actual: 30/05/2019

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

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

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

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

Anatomical Therapeutic Chemical (ATC) code

(B01AF01) rivaroxaban

rivaroxaban

(B01AF02) apixaban

apixaban

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 censured.

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)

Special population of interest

Other

Special population of interest, other

Prostate cancer patients

Estimated number of subjects

99.999

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

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)

Study report

20653_Study Report_Redacted_V1.0_2021-08-23.pdf (1.48 MB)

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)

Disease registry

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