Observational Studies in Cancer Associated Thrombosis for Rivaroxaban in SwEden (OSCAR-SE)

First published: 19/11/2021

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Study Finalised

Administrative details

EU PAS number

EUPAS43355

Study ID

46344

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

This is an observational study in which patient data from the past on venous thromboembolism (VTE) in patients with cancer is studied. VTE is a condition in which a patient has problems due to the formation of blood clots in the veins. People who have cancer have an increased risk of developing VTE. Three main types of anticoagulation treatments (“blood thinners”) have been available for patients with cancer who also have VTE, i.e. Low molecular weight heparins (LMWHs), Vitamin K antagonists (VKAs) and Non-vitamin K antagonist oral anticoagulants (NOACs). The treatment rivaroxaban belongs to the NOACs. Compared to other treatments available to patients who have cancer and VTE, NOACs may cause fewer medical problems and can be easier for patients to take correctly. In this study, the researchers will collect data about: • the type of VTE treatments given and for how long the treatments are taken • the risk of blood clots returning in the veins after treatment cessation, any events of major bleeding, and the number of deaths in patients with cancer The researchers will compare this information in the patients who received rivaroxaban versus LMWHs and NOACs versus LMWHs respectively. The researchers will look at the health information from adult patients in Sweden who were diagnosed with cancer between 2013 and 2019 and also have VTE. The researchers will collect this information from Swedish health registers including the Cancer Registry, National Patient Registry, Prescribed Drug Registry, and Cause of Death Registry.

Study status

Finalised

Research institutions and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

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

Planned: 30/08/2021

Actual: 30/08/2021

Study start date
Planned: 15/03/2022

Actual: 18/03/2022

Date of final study report
Planned: 31/03/2023

Actual: 05/05/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

21616_Study Protocol_Redacted_V1.0_2021-08-30.pdf(1.15 MB)

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:

- To estimate the risk of recurrent VTE, major bleeding and all-cause death in individuals with cancer - To describe the anticoagulation treatments for VTE - To estimate the risk of a recurrent VTE, major bleeding and all-cause death - To compare incidence rates of recurrent VTE, major bleeding and death in subjects treated with rivaroxaban versus LMWH, and NOACs versus LMWH

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AA03) warfarin

warfarin

(B01AB01) heparin

heparin

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AF01) rivaroxaban

rivaroxaban

(B01AF02) apixaban

apixaban

(B01AF03) edoxaban

edoxaban

Medical condition to be studied

Embolism venous

Population studied

Short description of the study population

The study population comprised of patients aged 18 years or older diagnosed with cancer of a subsequent venous thromboembolism (VTE) identified from the Swedish registries for the period of January 1, 2013 to December 31, 2020.

Inclusion criteria:

• a resident in Sweden of 18+ years of age
• a Swedish Person Identification Number
• a diagnosis of cancer (ICD10 = C00-C97) in the Swedish Cancer registry during 2013-2019 and a diagnosis of VTE subsequent to the cancer diagnosis.

Exclusion criteria:
• a diagnosis of atrial fibrillation, total hip or knee replacement or acute coronary syndrome (for evaluation of treatment patterns) before the date of VTE diagnosis
• a dispensed prescription for any OAC before the date of VTE diagnosis
• a cancer diagnosis associated with high bleeding risk (see listed diagnoses to be included)

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

Other

Special population of interest, other

Patients with venous thromboembolism

Estimated number of subjects

15000

Study design details

Outcomes

- Recurrence of VTE - Major bleedings - All-cause death - Choice of anticoagulation treatments for VTE - Duration of anticoagulation treatments for VTE - Recurrence of VTE with different treatment types of LMWH, VKA and NOAC - Major bleedings with different treatment types of LMWH, VKA and NOAC - All-cause death with different treatment types of LMWH, VKA and NOAC

Data analysis plan

Descriptive statistics, incidence rates and Cox proportional hazards regression models.

Documents

Study results

21616_EU PAS Abstract_Redacted_V1.0_2023-04-12.pdf(165.34 KB)

Study report

21616 Study Report_Redacted_V 1.0_2023-04-12.pdf(1.42 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 source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Cancer Registry Sweden, National Patient Registry Sweden, Cause of Death Registry Sweden

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

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