Observational Studies in Cancer Associated Thrombosis for Rivaroxaban – United Kingdom Cohort (OSCAR—UK)

First published: 29/10/2021

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS43329

Study ID

48920

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Patients with cancer are more likely than those without cancer to develop blood clots (deep vein thrombosis and pulmonary embolism), which are treated using blood thinners (anticoagulants). When clots occur, cancer patients carry a higher risk of recurring clots and more likely to bleed on blood thinning treatments. Therefore, it is critical to use blood thinners that optimize the safety and benefits. There are two main types of blood thinners that are recommended. The tablets which are direct-acting oral anticoagulants and the injections (low molecular-weight heparin). Clinical trials show the tablets may reduce clot risk but may potentially lead to more frequent bleeding, particularly in those with certain risk factors such as stomach ulcers, previous bleeding problems, certain cancer type. We aim to examine the effectiveness and safety of the tablets versus the injections for treatment of clots in cancer patients, to better understand these treatments' benefits and risks.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

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Institution

Contact details

Study institution contact

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

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/09/2021

Actual: 15/09/2021

Study start date

Planned: 02/12/2021

Actual: 02/12/2021

Date of final study report

Planned: 31/07/2022

Actual: 26/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

22020_Study Protocol_Redacted_V1.0_2021-08-23.pdf (522.21 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:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Evaluate the effectiveness (recurrent venous thromboembolism (VTE)) and safety (major bleeding and bleeding-related hospitalization) of rivaroxaban and other direct-acting oral anticoagulants (DOACs) vs. low molecular weight heparin (LMWH) for treatment of cancer-associated thrombosis (CAT) in the UK Clinical Practice Research Datalink (CPRD) dataset.

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

(B01AB04) dalteparin

dalteparin

(B01AB05) enoxaparin

enoxaparin

(B01AB10) tinzaparin

tinzaparin

Medical condition to be studied

Embolism venous

Population studied

Short description of the study population

The study focused on adults diagnosed with active cancer who experienced hospitalization, emergency department admission, or primary care visit with an incident venous thromboembolism (VTE), being administered rivaroxaban or other direct acting oral anticoagulants (DOACs) or a low molecular weight heparin (LMWH) on or after January 1, 2013 identified from the CPRD GOLD and Aurum HES-linked dataset.

Inclusion criteria:

• Be ≥18 years of age at the time of anticoagulation initiation

• Have active cancer and acute DVT and/or PE

• Treated with rivaroxaban (or any DOAC) or LMWH as their first recorded anticoagulant prescription 7 to 30 days post-acute CAT event diagnosis

• Have been active in the data set for at least 12-months prior to the index event and had at least one provider visit in the 12-months prior to the acute VTE event

Exclusion criteria:

• Evidence of atrial fibrillation, recent hip/knee replacement (with 90 days of CAT), ongoing VTE
treatment, valvular heart disease defined as any rheumatic heart disease, mitral stenosis or mitral valve repair/replacement
• History of inferior vena cava filter before cohort entry
• VKA use between cohort entry and index day (initiation of DOAC or LMWH)
• Evidence of any type of therapeutic anticoagulation use during all available look-back period per written prescription or patient self-report
• Initiation of rivaroxaban or other DOACs or LMWH during the study period at non-therapeutic doses (e.g., enoxaparin at a dose other than 1 mg/kg twice daily or 1.5 mg/kg once daily; dalteparin at a dose other than 200 IU/kg of total body weight)
• Pregnancy
• Recording indicative of palliative care before cohort entry
• Any clinically-relevant bleeding-related d hospitalization or VTE recurrence between the initial CAT and the start of observation

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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)

Special population of interest

Other

Special population of interest, other

Venous thromboembolism patients

Estimated number of subjects

5000

Study design details

Outcomes

- The risk of recurrent VTE at 3-months - Composite of any major bleeding or clinically-relevant non-major bleeding-related hospitalization (per the International Society on Thrombosis and Haemostasis (ISTH) criteria 9, 10 for identification of bleeding-associated hospitalizations) at 3-months - All-cause mortality at 3-months, - Recurrent VTE at 6- and 12-months post-index VTE - Composite of any major or clinically-relevant nonmajor bleeding-related hospitalization at 6- and 12-months post-index VTE, including: -- Intracranial hemorrhage (ICH) To see the full list of secondary outcomes please refer to the protocol.

Data analysis plan

Overlap weighting will be used to adjust for potential confounding between treatment cohorts (exposures of interest). Patients receiving rivaroxaban will also be 1:1 matched to LMWH patients based on propensity scores. Analysis of the primary effectiveness and safety endpoints by key subgroups will be performed as well.

Documents

Study results

22020_EU PAS Abstract_Redacted_V1.0_2022-08-26.pdf (272.77 KB)

Study report

22020_Study_Report_Redacted_V1.0_2022-08-26.pdf (724.8 KB)

Data management

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)

Clinical Practice Research Datalink

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