DARWIN EU® – Incidence rates of venous thromboembolic events in patients with selected cancers

First published: 15/01/2025

Last updated: 31/01/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000440

EU PAS number

EUPAS1000000440

Study ID

1000000440

DARWIN EU® study

Yes

Study countries

☐ Belgium

- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] Germany
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

The association between cancer and thromboembolic events was assessed in various studies. In a large cohort of cancer patients, the incidence of thromboembolic events was found to be higher in cases of renal cell, ovarian, pancreatic, stomach, and lung cancers, as well as acute myelogenous leukemia and non-Hodgkin lymphoma during the four months immediately preceding the cancer diagnosis (White, 2005).

The prevalence of thromboembolic events at the time of diagnosis was highest for pancreatic cancer and lowest for breast cancer in another registry-based study (Ohashi, 2020). The risk of thromboembolic events was increased for all cancer types in another study conducted in the United States (Petterson, 2015). The incidence of thromboembolic events increased during the first few months of chemotherapy in a cohort of cancer patients followed for up to 12 months, with higher odds observed in pancreatic, gastric, and lung cancers (Khorana, 2013).

Certain cancer medications have also been associated with higher risks of thromboembolic events (Nalluri, 2008; Khorana, 2013). Additionally, major surgery is known to be associated with thromboembolic events, with an increased risk that persists for 90 to 120 days post-surgery (Björklund, 2024).

A high rate of recurrent thromboembolic events is observed over time following the discontinuation of anticoagulant therapy in patients with cancer-associated thrombosis (van Hylckama Vlieg, 2023).
When a potential safety signal of this nature (i.e. VTE associated with the use of a therapy) emerges in cancer populations, it can be challenging to assess the potential association without recent and reliable information on the background risk. This study addresses this knowledge gap by generating background incidence rates of thromboembolic events among patients with selected cancer types.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution **Educational Institution** **ENCePP partner**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anton Barchuk

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/07/2024

Actual: 03/07/2024

Study start date

Planned: 10/01/2025

Actual: 10/01/2025

Date of final study report

Planned: 15/07/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C3-005_Thromboembolic events in cancers_V5.pdf

(993.8 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study topic, other:

Cancer, thromboembolism

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

This will be a population-level descriptive epidemiology and patient-level characterisation study.

Main study objective:

1. To estimate the incidence rates of thromboembolic events in patients newly diagnosed with each type of selected cancers stratified by country/database, age group, sex, study period (2016-2019 and 2020-2022), and cancer stage one and two years after cancer diagnosis.

2. To characterise cancer patients in terms of demographics, comorbidities and concomitant medication before and at the time of diagnosis, as well as medications and procedures received in the first 90 days after cancer diagnosis.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Bone cancer

Breast cancer

Colorectal cancer

Leukaemia

Lymphoma

Ovarian cancer

Hepatic cancer

Prostate cancer

Endometrial cancer

Skin cancer

Gastrooesophageal cancer

Pulmonary embolism

Pelvic venous thrombosis

Hepatic vein thrombosis

Retinal vein thrombosis

Disseminated intravascular coagulation

Additional medical condition(s)

Brain cancer, Kidney cancer, Lung cancer, Melanoma, Pancreatic cancer, Venous thromboembolism, Splanchnic vein thrombosis

Population studied

Short description of the study population

The study population will include all individuals aged 18 years and above with a primary diagnosis of selected cancers in the study period. Cancer types will include bone, brain, breast, colorectal, corpus uteri, kidney, leukemia and lymphoma, liver, lung, melanoma, esophageal, ovary, pancreas, prostate, and stomach.

Only patients with the first and one cancer diagnosis (except non-melanoma skin cancer) will be included.
Patients with prior cancer diagnosis (except non-melanoma skin cancer) will be excluded to make sure the outcomes are related to a single primary cancer type of interest patient and also to avoid possible misclassification of second primary cancer and metastatic disease from previously diagnosed primary

cancer.

Cancer cases and thromboembolic events will be identified using appropriate computable phenotyping algorithms. Conditions in the OMOP CDM use the Systematised Nomenclature of Medicine (SNOMED) as the standard vocabulary for diagnosis codes.

For cancer diagnoses, the International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3) will also be considered. Algorithms to reproduce cancer phenotypes will be shown along with the study results.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

This study will use routinely collected health data from 10 databases from 8 European countries.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink (CPRD) GOLD

Danish Health Data Registries

Estonian Biobank

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

IQVIA Longitudinal Patient Data - Belgium

IQVIA Disease Analyzer Germany

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

UK Biobank

Data source(s), other

FinOMOP-HUS

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown