DARWIN EU® - Sex differences in treatment patterns for venous thromboembolic events in European countries

First published: 06/08/2026

Last updated: 06/08/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000001079

Study ID

1000001079

DARWIN EU® study

Yes

Study countries

- Denmark
- Finland
- Netherlands
- Spain

United Kingdom

Study description

While potential sex differences in cardiovascular treatment have been widely discussed, existing evidence remains fragmented. In particular, there is a lack of consistent, large-scale Real-World Evidence to objectively assess whether meaningful treatment gaps exist across European healthcare systems in routine clinical practice. For venous thromboembolic events (VTE), sex differences in anticoagulation treatment may arise from variations in bleeding risk, pharmacokinetics, and hormonal influences such as oral contraceptives and hormone replacement therapy (HRT). Important evidence gaps remain regarding anticoagulant treatment strategies in females, particularly the concomitant use of anticoagulants with hormonal contraception and HRT. Consequently, the current clinical guideline recommended has adapted anticoagulant treatments for individuals with renal impairment, cancer, or extreme under/overweight. Evaluating differences in treatment choice and switching patterns between males and females may provide valuable insights into routine clinical practice and potential gaps in care.
As part of the broader European Medicines Agency (EMA) Women's Health Initiative, this study aims to evaluate potential sex differences in anticoagulant treatment for VTE. By examining sex-specific patterns in treatment initiation and subsequent treatment pathways, the study seeks to identify potential gaps in care that may inform clinical practice, regulatory decision-making, and public health strategies aimed at promoting equitable, evidence-based treatment.

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
- Greece
- Hungary
- Italy
- Netherlands
- Norway

Portugal

Spain

Sweden

United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Ivan Lam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/06/2026

Actual: 08/06/2026

Study start date

Planned: 22/07/2026

Actual: 22/07/2026

Date of final study report
Planned: 20/11/2026

Sources of funding

- EMA

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A (new user) cohort study will be conducted using routinely collected health data from 5 data sources from 5 countries across Europe and in 4 European Union (EU) member states

Main study objective:

1. To describe anticoagulant treatment initiation for venous thromboembolic events in males and females
2. To describe drug utilisation of anticoagulant treatments, including initial treatment duration and initial dose, in males and females
3. To describe and compare anticoagulant treatment switching and combination patterns for venous thromboembolic events in males and females

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Anticoagulants (ATC code B01)

Anatomical Therapeutic Chemical (ATC) code

(B01) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Medical condition to be studied

Venous thrombosis

Population studied

Short description of the study population

Objective 1 (Characterisation of first-line anticoagulant treatment)

Inclusion criterion: Diagnosis of VTE during the recruitment period

Exclusion criteria

• Age <18 years at first VTE event (index date)

• Less than 365 days of available history before the index date

• Record of VTE event before study start (01/01/2015)

• Record of prescription/dispensation of anticoagulants before the index date

Objectives 2 and 3 (Drug utilisation of first-line treatment and switching patterns)

Inclusion criteria

• Diagnosis of VTE during the recruitment period

• Initiation of anticoagulant drug treatment within 90 days after diagnosis (index date)

Exclusion criteria

• Age <18 years on the date of anticoagulants treatment initiation

• Less than 365 days of available history before date of anticoagulants

treatment initiation

• Record of VTE before study start 01/01/2015

• Record of anticoagulant drug prescription/dispensation before diagnosis of first VTE event

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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)

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)

Danish Health Data Registries

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

Clinical Practice Research Datalink (CPRD) GOLD

Data source(s), other

FinOMOP-THL

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/cdm54.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No