ChaRactErization of patients following aCute venous thrOmboembolism (VTE) and assessment of safety and effectiveness of dabigatran etexilate (DE) in the tReatment and secondarY prevention of acute deep vein thrombosis (DVT) and pulmonary embolism (PE) in comparison to vitamin K antagonist (VKA) in routine clinical practice - RE-COVERY DVT/PE

First published: 21/10/2015

Last updated: 17/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS11368

Study ID

34224

DARWIN EU® study

No

Study countries

- Argentina
- Austria
- Belgium
- Brazil
- Bulgaria
- Canada
- Chile
- Colombia
- Ecuador
- Egypt
- Germany
- Greece
- Hungary
- Italy
- Korea, Republic of
- Latvia
- Lebanon
- Malaysia
- Mexico
- Netherlands
- New Zealand
- Peru
- Philippines
- Poland
- Portugal
- Romania

- Russian Federation
- Saudi Arabia
- Serbia
- Slovakia
- Slovenia
- Sweden
- Thailand
- Türkiye
- United Arab Emirates
- United Kingdom
- United States
- Viet Nam

Study description

RE-COVERY is a large, multi-national, multi-center non-interventional study based on new data collection. The study will enroll and characterize patients within 30 days of being diagnosed with an acute DVT and/or PE. The study has two main objectives. Objective 1 willcharacterize the DVT / PE patient population. All patients with a DVT and/or PE will be enrolled for cross-sectional characterization of the VTE patient population. Objective 2 will compare the safety and effectiveness of dabigatran etexilate regimens for treatment of VTE in comparison to VKA regimens. Patients treated with dabigatran etexilate or VKA will befollowed up for the occurrence of outcome events for up to one year.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Boehringer Ingelheim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/09/2014

Actual: 15/09/2014

Study start date

Planned: 18/01/2016

Actual: 03/02/2016

Date of final study report
Planned: 17/04/2020

Actual: 18/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1160_188_REDACTED PROTOCOL.pdf (796.73 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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

RE-COVERY is a large, multi-national, multi-centre observational study based on new data collection. The study enrolled and characterised patients diagnosed with an acute DVT and/or PE from 229 sites from 5 regions:
Europe, North America, Middle East, Asia and Latin America.

Main study objective:

Objective 1: To characterize the DVT/PE patient population including the initial acute event phase.Objective 2: To analyze the safety and effectiveness of dabigatran etexilate regimens in the treatment of DVT and PE over 1 year of follow-up in comparison to a VKA regimen.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

DABIGATRAN ETEXILATE

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AA) Vitamin K antagonists

Vitamin K antagonists

(B01) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Medical condition to be studied

Deep vein thrombosis

Pulmonary embolism

Population studied

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)

Estimated number of subjects

14000

Study design details

Setting

Participation of a country required the approval of dabigatran for the VTE indication prior to study initiation within that country. Selected sites withineach country included those physicians (e.g., specialist and general practitioners) and facilities (e.g., general practice offices, specialist offices, hospitals, outpatient care centres and anticoagulation clinics) that reflected the clinical practice within that country.

Outcomes

For Objective 1, the primary outcomes are:-Demographic information (age and gender)-VTE event information (event type and treatment for event)For Objective 2, the primary outcomes are:-Primary safety outcome measure: ISTH Major bleeding-Primary effectiveness outcome measure: symptomatic recurrent VTE including VTE-related mortality, In Objective 2 patients, the secondary outcomes are:-recurrent DVT-recurrent PE-recurrent DVT and PE-VTE-related mortality-all-cause mortality

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Data analysis plan

Patient demographics and baseline characteristics will be summarized descriptively. Multivariable regression models and propensity score based methods will be used for the comparative analyses of dabigatran etexilate and VKA patients.

Documents

Abstract of study report

1160-0188_Synopsis.pdf (274.41 KB)

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)

Other

Data sources (types), other

Prospective patient-based data collection

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