Real-world Study on Bemiparin Effect in Patients with Cancer-Associated Thromboembolism Using Artificial Intelligence (BEMICAT Study)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000578

Study ID

1000000578

DARWIN EU® study

No

Study countries

☐ Spain

Study description

BEMICAT is a multicenter, retrospective, non-interventional study designed to evaluate the effectiveness and safety of bemiparin compared with other low molecular weight heparins (LMWHs)—dalteparin, enoxaparin, and tinzaparin—in the management of cancer-associated thrombosis (CAT).
CAT, which typically presents as deep vein thrombosis (DVT) or pulmonary embolism (PE), remains a leading cause of morbidity and mortality in cancer patients despite being preventable.

The study emulates a target trial and uses real-world data from electronic health records (EHRs) of Spanish hospitals, leveraging natural language processing (NLP) and machine learning (ML) technologies (EHRead®) to extract structured information from unstructured clinical texts. Data will be collected from 2014 to 2025 and analyzed in two sequential phases.
Phase I is a feasibility assessment;
Phase II, contingent upon Phase I success, will estimate the per-protocol effects of long-term, full-dose anticoagulation with bemiparin versus pooled comparators.
Adult cancer patients with objectively confirmed acute DVT or PE will be included if they initiated anticoagulation with LMWHs within a defined time frame.
Key outcomes include recurrence of venous thromboembolism and major bleeding over a 7-month follow-up. Secondary outcomes include patient characteristics, treatment pathways, time-to-event analyses, and validation of NLP-based data definitions.
This study addresses a major gap in the comparative evidence on bemiparin use in CAT and will provide real-world evidence to inform clinical practice and support regulatory decisions.

Study status

Ongoing

Research institutions and networks

Institutions

LABORATORIOS FARMACÉUTICOS ROVI, S.A.

Contact details

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Study timelines

Date when funding contract was signed

Actual: 26/08/2024

Study start date

Actual: 10/09/2024

Data analysis start date

Planned: 26/05/2025

Actual: 27/06/2025

Date of interim report, if expected

Planned: 01/06/2025

Actual: 23/07/2025

Date of final study report

Planned: 01/03/2027

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

ROVI_BEMICAT_Protocol_V1.1_27FEB2025_FE.pdf (2.62 MB)

ROVI_BEMICAT_Protocol_V1.2_11JUN2025_FE.pdf (2.03 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:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Multicenter, retrospective, observational cohort study emulating a target trial, using electronic health records and NLP to compare the effectiveness and safety of bemiparin versus other LMWHs in cancer-associated thrombosis.

Main study objective:

The main objective of the BEMICAT study is to assess the non-inferiority of long-term, full-dose treatment with bemiparin in preventing recurrent venous thromboembolism (VTE) in adult patients with cancer-associated thrombosis (CAT), compared to pooled data from patients treated with dalteparin, enoxaparin, or tinzaparin. Effectiveness will be evaluated over a six-month period following the index thrombotic event.

In addition, the study aims to compare the safety profile of bemiparin versus the comparator low molecular weight heparins (LMWHs), with particular attention to the incidence of major bleeding events during the same follow-up period.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is a retrospective, multicenter observational cohort study designed as a target trial emulation.
It uses real-world data from electronic health records (EHRs) to assess the comparative effectiveness and safety of bemiparin versus other low molecular weight heparins in patients with cancer-associated thrombosis (CAT).

The study identifies a cohort of adult patients with active cancer and objectively confirmed venous thromboembolism (VTE), and follows them from the time of diagnosis (time zero) for seven months.
Patients are classified according to the anticoagulant received, and only those treated with full-dose, long-term therapy are included in the per-protocol analysis.
The design emulates key elements of a randomized trial, including eligibility criteria, alignment of follow-up with treatment initiation, and prespecified censoring rules.
Data are extracted using natural language processing (NLP) and machine learning (ML) technologies to convert unstructured clinical texts into structured variables for analysis.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AB12) bemiparin

bemiparin

(B01AB04) dalteparin

dalteparin

(B01AB05) enoxaparin

enoxaparin

(B01AB10) tinzaparin

tinzaparin

Additional medical condition(s)

cancer-associated thrombosis

Population studied

Short description of the study population

The study will include adult patients (aged ≥18 years) with active cancer and an objectively confirmed diagnosis of cancer-associated thrombosis (CAT), defined as deep vein thrombosis (DVT), pulmonary embolism (PE), or both. Active cancer will be defined as a cancer diagnosis, cancer treatment, or metastatic disease within the six months prior to the thrombotic event, or a hematologic malignancy not in complete remission.
Patients will be identified from participating Spanish hospitals between January 2015 and June 2024, and will have initiated long-term anticoagulation with bemiparin, dalteparin, enoxaparin, or tinzaparin.
Pregnant individuals, those with only non-melanoma skin cancer or basal cell carcinoma, and patients with a prior VTE episode within 12 months before the index event will be excluded.

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)

Special population of interest

Other

Special population of interest, other

The study is restricted to adult cancer patients with venous thromboembolism and does not include specific analyses of special populations beyond the target population.

Estimated number of subjects

5900

Study design details

Setting

This study will be conducted using EHRs from multiple hospitals across Spain. The study period spans from January 1, 2014 to January 31, 2025, with the recruitment period from January 1, 2015 to June 30, 2024.
The population includes adult patients (≥18 years) with active cancer and objectively confirmed VTE (DVT, PE, or both). Patients will be identified using NLP applied to unstructured EHR data, complemented by structured clinical variables.
Patients will be assigned to treatment arms based on the LMWH received:

bemiparin (exposed group) versus pooled comparators (dalteparin, enoxaparin, tinzaparin).
Follow-up will begin at the time of CAT diagnosis (time zero) and will continue for 6 months or until censoring due to treatment discontinuation or switch, recurrent VTE, death, loss to follow-up, or administrative study end.

Comparators

The comparators in this study are LMWHs commonly used for the treatment of CAT: dalteparin, enoxaparin, and tinzaparin.
These will be pooled into a single comparator group and analyzed against bemiparin in a per-protocol framework. Treatment allocation is not randomized but based on real-world prescribing patterns captured in EHRs.
Patients included in the comparator group must meet the same eligibility criteria and receive long-term, full-dose LMWH therapy, initiated within the defined time window after the index CAT event.

Outcomes

The study will evaluate effectiveness, safety, and treatment-related outcomes during a six-month follow-up period after the index CAT event. The primary effectiveness outcome is symptomatic VTE recurrence.
Secondary effectiveness outcomes include incidental VTE recurrence, stroke, acute myocardial infarction, and all-cause death.
The primary safety outcome is major bleeding.
Secondary safety outcomes include clinically relevant non-major bleeding and other clinically relevant bleeding events.
Treatment-related outcomes will assess anticoagulation patterns, including persistence and treatment switches between LMWHs.

Data analysis plan

Phase I will estimate the annual incidence of CAT in patients initiating long-term treatment with bemiparin using a predictive model adjusted for hospital type, population, and year.
Phase II will assess the per-protocol effect of bemiparin versus pooled LMWHs (dalteparin, enoxaparin, tinzaparin) in preventing VTE recurrence and evaluating safety over 6 months, following a target trial emulation framework. Risk estimation for time-to-event outcomes will use weighted pooled logistic regression, with a noninferiority margin of 1.5. Cloning, censoring, and time-varying inverse probability weighting will address treatment assignment and selection bias. Effect modification (e.g., index DVT vs PE) will be included in model specification.

Descriptive statistics will summarize baseline characteristics, treatment patterns, and switch rates. Cumulative incidence functions will be used to estimate time-to-event outcomes accounting for competing risks.
Validity of NLP-extracted population, intervention, and outcome definitions will be assessed against a reference standard by a blinded adjudication committee using sensitivity, specificity, PPV, NPV, and ICC.
Missing data will not be imputed; results will reflect observed data and missingness will be reported explicitly.

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)

Other data source

Data source(s), other

Electronic Health Records from study sites

Data sources (types)

Drug prescriptions

Drug registry

Electronic healthcare records (EHR)

Laboratory tests and analyses

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

Not applicable

Procedures

Procedure of data extraction

ROVI_BEMICAT_Protocol_V1.1_27FEB2025_data extraction.pdf

English (950.64 KB - PDF)

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