

# Benefit and risk of AntiThrombotic Treatments after Orthopaedic Surgery in real-life settings: a cohort study in the SNIIRAM claims and hospitalisation database (ATTOS)

**First published:** 18/11/2015

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS11521

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### Study ID

49831

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### DARWIN EU® study

No

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### Study countries

 France

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## **Study description**

Eliquis® (apixaban), an antithrombotic agent has obtained market authorization in the indication “Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip or knee replacement surgery (THR or TKR)”. In this context, the French Transparency Commission requested a cohort study of patients treated in France by Eliquis® under real-life condition. To adress the HAS request, an historical cohort study will be formed using a national healthcare claims (SNIIRAM) linked to the national hospital-discharge summaries database. This cohort will include all adults with an antithrombotic agent reimbursement within one week after discharge for an orthopaedic procedure (THR, TKR and other orthopaedic procedures) between 1 January 2013 and 30 September 2014, and with a 3-year database history and a follow-up of 3 months. The primary objectives of the study are to estimate the cumulative incidence of VTE (effectiveness) and the cumulative incidence of clinically significant bleeding (safety) in real-life clinical settings in France after a THR, a TKR, and after another orthopaedic procedure over a 3-month post-surgery period, according to the initial antithrombotic treatment. The secondary objectives are to estimate the cumulative incidence of all-cause death after a THR, after a TKR, and after another orthopaedic procedure, to compare cumulative incidence of VTE, of clinically significant bleeding, and of all-cause death over a 3-month post surgery period between Eliquis® and other antithrombotic, to describe the treated population, to describe conditions of Eliquis® use and other antithrombotic treatments, and to assess the impact of each antithrombotic treatment on the healthcare system during the study period. The statistical analysis will be performed separately for THR, TKR, and other orthopaedic procedures, according to the treatment group (first antithrombotic agent dispensed within a week after discharge).

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## **Study status**

Finalised

## **Research institutions and networks**

# Institutions

## Bordeaux PharmacoEpi, University of Bordeaux

 France

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**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

Not-for-profit

ENCePP partner

## Contact details

### Study institution contact

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Study contact

[plateforme.bpe@u-bordeaux.fr](mailto:plateforme.bpe@u-bordeaux.fr)

### Primary lead investigator

Patrick BLIN

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 17/04/2015

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**Study start date**

Planned: 01/04/2016

Actual: 15/06/2016

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**Data analysis start date**

Planned: 31/05/2016

Actual: 15/09/2016

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**Date of final study report**

Planned: 31/10/2016

Actual: 29/05/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bristol-Myers Squibb

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness  
Drug utilisation  
Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To estimate the cumulative incidence of VTE (effectiveness) and the cumulative incidence of clinically significant bleeding (safety) in real-life clinical settings in France after a THR, after a TKR, and after another orthopaedic procedure over a 3-month post-surgery period, according to the initial antithrombotic treatment.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(B01A) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

(B01AF02) apixaban

apixaban

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## **Medical condition to be studied**

Orthopaedic procedure

Venous thrombosis

## **Population studied**

### **Short description of the study population**

Adults patients with venous thromboembolic events (VTE) identified from the national healthcare claims data base (SNIIRAM) who had undergone elective total hip or knee replacement surgery (THR or TKR) and has been treated with Eliquis® (apixaban) between 1 January 2013 and 30 September 2014.

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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)
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### **Special population of interest**

Other

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## **Special population of interest, other**

Patients with orthopaedic procedure and venous thrombosis

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## **Estimated number of subjects**

300000

# Study design details

## **Outcomes**

Primary effectiveness outcome: VTE defined as a main diagnosis of pulmonary embolism or deep vein thrombosis (effectiveness) in hospital-discharge summaries over a 3-month period after index date. Primary safety outcome: Clinically significant bleeding defined as main diagnosis of bleeding (safety), in hospital-discharge summaries over a 3-month period after index date.

Secondary effectiveness outcome: VTE defined as primary effectiveness criteria or new dispensation of a Low-Molecular-Weight Heparin following a specific examination for pulmonary embolism or VTE, over a 3-month period after index date. All-cause death defined as any cause of death over 3-month period after index date.

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## **Data analysis plan**

Statistical analysis will be performed using SAS® software. A Statistical Analysis Plan will be developed and validated by the Scientific Committee before analysis. The statistical analysis will be performed separately for THR, TKR and other orthopaedic procedures, according to the treatment group. The analysis will describe the cumulative incidence of primary/secondary effectiveness endpoint and primary safety endpoint, the patient and disease characteristics, the conditions of Eliquis® and other antithrombotic agent use, the healthcare consumption, and compared outcomes between Eliquis® and other antithrombotic agents. For primary outcomes, a more sensitive definition using

main, related, or associated diagnosis will be used for sensitivity analysis.

## Documents

### Study publications

[Blin P, Samama CM, Sautet A, Benichou J, Lignot-Maleyran S, Lamarque S, Lorrain...](#)

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## 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

Hospital Discharge

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No