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

Study ID

49831

DARWIN EU® study

No

Study countries

☐ France

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).

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/12/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Patrick BLIN plateforme.bpe@u-bordeaux.fr

Study contact

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

Study start date
Planned: 01/04/2016

Actual: 15/06/2016

Data analysis start date
Planned: 31/05/2016

Actual: 15/09/2016

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

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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

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

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.

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)

Special population of interest

Other

Special population of interest, other

Patients with orthopaedic procedure and venous thrombosis

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.

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 separetely 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…

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No