

# Secondary Prevention of Acute Coronary Events with Antiplatelet Agents: A cohort study in the SNIIRAM database (SPACE-AA)

**First published:** 06/03/2014

**Last updated:** 23/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5987

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### Study ID

49886

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### DARWIN EU® study

No

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### Study countries

 France

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### Study description

The research question is to evaluate in real-life the use and the impact of ticagrelor and other antiplatelet agent (APA) in the secondary prevention of acute coronary syndrome (ACS). The main objective of effectiveness is to estimate the one-year incidence of the primary effectiveness endpoint (all-cause death, or hospitalisation for ACS, or hospitalisation for ischemic or undefined stroke) during ticagrelor exposure and during other APA exposure for secondary prevention of ACS. The main objective of safety is to estimate the one-year incidence of the primary safety endpoint (hospitalisation for major bleeding) during ticagrelor exposure and during other APA exposure for secondary prevention of ACS. The study is a cohort study in a national healthcare claims and hospitalisations database, of patients hospitalized in 2013 for an ACS with one-year previous history and at least one year follow-up in the database. APA exposure will be defined by claims for drug dispensation after discharge. For each APA, exposure will be defined by the first APA dispensation in the month after discharge, and the time between index ACS and last dispensation + 37 days (30 days of treatment + one week). The follow-up period after index ACS is at least one and up to two years, until 31 December 2014. The study period is defined by the years 2012 to 2014. The study population will be all patients hospitalised between 1 January and 31 December 2013 for an ACS, regardless of the type of treatment. According to the protocol, about 150 000 patients are hospitalised yearly at least once with a main diagnosis of unstable angina or myocardial infarction (MI). Taking into account the PLATO results, around 15 000 (10%) of death, MI or non-fatal stroke are expected after one year of follow-up.

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## **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

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Study contact

[patrick.blin@u-bordeaux.fr](mailto:patrick.blin@u-bordeaux.fr)

### Primary lead investigator

Nicholas Moore

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 26/11/2013

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**Study start date**

Actual: 10/02/2015

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**Date of final study report**

Actual: 20/12/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Aztrazeneca

## 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  
Disease epidemiology  
Drug utilisation  
Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Main objective of effectiveness: Estimate the 1-year incidence of the primary effectiveness endpoint (all-cause death, hospitalisation for ACS, or for ischemic or undefined stroke) during ticagrelor exposure and during other APA exposure for secondary prevention of ACS. Main objective of safety: Estimate the 1-year incidence of the primary safety endpoint (hospitalisation for major bleeding).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

(B01AC) Platelet aggregation inhibitors excl. heparin

Platelet aggregation inhibitors excl. heparin

(N02BA01) acetylsalicylic acid

acetylsalicylic acid

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### **Medical condition to be studied**

Acute coronary syndrome

## Population studied

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

Subject with acute coronary syndrome treated with ticagrelor and other antiplatelet agents obtained from the national healthcare claims and hospitalisations database for the study period of 2012 to 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 acute coronary syndrome

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## **Estimated number of subjects**

150000

# Study design details

## **Outcomes**

The primary effectiveness endpoint is a composite of all-cause death, hospitalisation for ACS, and hospitalisation for an ischemic or undefined stroke. The primary safety endpoint includes following events: hospitalisation for bleeding events (including haemorrhagic stroke). The secondary effectiveness endpoint is a composite of all-cause death, hospitalisation for ACS, hospitalisation for percutaneous coronary intervention or coronary artery bypass grafting, and hospitalisation for an ischemic or undefined stroke.

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## **Data analysis plan**

Statistical analysis will be carried out according to a documented and approved Statistical Analysis Plan (SAP). The SAP describes statistical analysis as foreseen at the time of planning study. Statistical analysis will be performed after database lock using SAS® software (SAS Institute, last version, North Carolina, USA). Blind double programming will be used for the main outcome measures. Primary and secondary endpoints will be analysed using survival methods: The Kaplan Meier estimate for incidence of events and the Cox proportional hazard risk model to compare incidence between APA, with gender, age, initial SCA management and high-dimensional propensity score (hdPS) adjustment and matching.

# Documents

## **Study publications**

[Blin P, Dureau-Pournin C, Benichou J, Bonello L, Dallongeville J, Danchin N, Fa...](#)

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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**

National healthcare insurance and hospital-discharge summary database  
France

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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