Real-life anticoagulants benefit-risk in atrial fibrillation (AF) in France: VKA benefit-risk assessment before DOAC use for AF (ENGEL 1 VKA)

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# Administrative details

**Study description** 

EU PAS number	
EUPAS6616	
Study ID	
49877	
DARWIN FILO strate	
DARWIN EU® study	
No	
Study countries	
France	

The research question is to assess the baseline short-term, medium-term and long-term benefit-risk of vitamin K antagonists (VKA) for new users in the indication of atrial fibrillation (AF). The main objective is to estimate the 6month, 1-year, and 3-year risk of major bleeding, arterial thrombotic events (stroke, systemic embolism), myocardial infarction (MI) and death during VKA exposure. This is a cohort study in a national healthcare claims and hospitalisations database including new users of VKA for AF between 01/01/2007 and 31/12/2011 with a follow-up until 31/12/2012, and 2 years history. VKA exposure will start at the date of first VKA dispensation (index date) and end at the date of VKA stop or at the end of follow-up. AF population will be defined as patients with full coverage for AF, hospitalisation or probabilistic AF information in the database, and without other probable cause of VKA prescription. Outcomes will be defined by primary diagnosis ICD-10 codes of hospital-discharge summary and date of death. The cumulative incidence of outcomes will be estimated using Kaplan-Meier estimate and 95% confidence interval.

### Study status

Finalised

## Research institutions and networks

## Institutions

Bordeaux PharmacoEpi, University of Bordeaux
France
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## Contact details

## Study institution contact

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Study contact

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### **Primary lead investigator**

Nicholas Moore

**Primary lead investigator** 

# Study timelines

## Date when funding contract was signed

Actual: 23/05/2014

### Study start date

Actual: 15/04/2014

### Date of final study report

Actual: 14/11/2014

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Boehringer Ingelheim

# 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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

The main objective is to estimate the 3-month, 1-year, and 3-year risk of major bleeding, arterial thrombotic events (stroke, systemic embolism), MI and death during VKA exposure for new VKA users in AF during drug exposure.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

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

(B01AA) Vitamin K antagonists

Vitamin K antagonists

#### Medical condition to be studied

Atrial fibrillation

# Population studied

#### Short description of the study population

The study participants were new users of vitamin K antagonists for the indication of atrial fibrillation identified from national healthcare claims and hospitalisations database between 1 January 2007 and 31 December 2011 with a follow-up until 31 December 2012, and 2 years history.

#### Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)</li>
- Adults (85 years and over)

### **Special population of interest**

Other

#### Special population of interest, other

Atrial fibrillation patients

#### **Estimated number of subjects**

5000

# Study design details

#### **Outcomes**

Major bleeding (MB) as hospitalisation with primary diagnosis of bleeding events including haemorrhagic stroke, Arterial thrombotic events (ATE) as hospitalisation with primary diagnosis of ischemic or undefined stroke or systemic arterial embolism, MI as hospitalisation with primary diagnosis of MI or acute coronary syndrome (ACS), All-cause of death, Composite criterion of MB/ATE/MI/death.

#### 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. Blind double programming will be used for the main outcome measures. The diagnosis of AF will be considered definite if a long-term disease or hospital discharge summary with the ICD-10 code I48 were recorded before the index date, and no other indication for VKA. In the absence of definite AF, probable AF will be defined using an AF disease score, that will be a logit function of patient characteristics, including specialty of first VKA prescriber, medical acts, lab tests and drugs (ATC codes). Primary outcomes will be analysed using survival methods: The Kaplan-Meier estimate for cumulative incidence of events.

## **Documents**

#### Study publications

Blin P, Dureau-Pournin C, Lassalle R, Abouelfath A, Droz-Perroteau C, Moore N.

# 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

EGB: permanent 197th random sample of the SNDS national claims database France

#### **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**

## **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No