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

First published: 23/05/2014

Last updated: 23/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6616

Study ID

49877

DARWIN EU® study

No

Study countries

France

Study description

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 6-month, 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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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

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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)
- 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

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No