# Real-world Comparisons of Stroke, Major Bleeding, Myocardial Infarction, Acute Limb Ischemia and Death among Non-Valvular Atrial Fibrillation Patients Diagnosed With Coronary Artery Disease/Peripheral Arterial Disease who Initiated Oral Anticoagulation Therapies (CAD PAD)

**First published:** 05/05/2017

**Last updated:** 31/03/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS18970

**Study ID**

23575

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

The study will be a longitudinal retrospective cohort analysis using the CMS fee-for-service (FFS) Medicare database. The study period will be from January 1, 2012 through December 31, 2014 or until the last date of the data cut available at the time of execution of the study.This study will evaluate the patient profiles, current antithrombotic patterns and real-world clinical outcomes among NVAF patients with CAD and/or PAD.Aim 1: To compare the risk of myocardial infarction (MI), stroke, acute limb ischemia, all-cause death and a composite of these endpoints among patients initiating OACs (warfarin, apixaban, rivaroxaban and dabigatran). Aim 2: To compare the risk of major bleeding among patients initiating OACs.Aim 3: To compare the risk of stroke and stroke/SE among patients initiating OACs.Aim 4: To compare healthcare resource use and costs among patients initiating different OACs.Aim 5: To describe the baseline demographic and clinical characteristics among patients initiating OACs (warfarin, apixaban, rivaroxaban and dabigatran)

**Study status**

Finalised

# Research institutions and networks

## Institutions

### SIMr STATinMED

**First published:** 01/02/2024

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Institution

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Di Fusco Manuela

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 02/01/2017

**Study start date**

Planned: 09/05/2017

Actual: 09/05/2017

**Date of final study report**

Planned: 11/04/2018

Actual: 11/04/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer

## Study protocol

Pfizer_CAD_PAD_NOAC NI Study Protocol_04MAY2017.pdf (795.05 KB)

## 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

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The main objective of this study is to collect and analyze clinical and cost-related outcome measures for treatment naïve NVAF patients on either apixaban or warfarin using a US claims database.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective cohort analysis

## Study drug and medical condition

**Medicinal product name**

ELIQUIS

PRADAXA

XARELTO

**Medicinal product name, other**

Coumadin

**Medical condition to be studied**

Atrial fibrillation

# Population studied

**Short description of the study population**

Adult patients who were prescribed oral anticoagulants were selected from the Medicare database between January 1, 2013 and December 31, 2014 or until the last date of the data cut available at the time of execution of the study.

**Age groups**

- 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 atrial fibrillation

**Estimated number of subjects**

10000

# Study design details

**Outcomes**

Bleeding-related outcomes, Health resource utilization/cost outcomes

**Data analysis plan**

Descriptive analyses, including means, medians, and standard deviations will be conducted for continuous variables. Numbers and percentages will be provided for dichotomous and polychotomous variables. Bivariate comparisons of baseline characteristics and outcomes measures will be provided. Appropriate tests will be used based on the distribution of the measure. The cumulative incidence rate for clinical outcomes will be calculated. Multivariate analysis or propensity score matching will be conducted.

## Documents

**Study results**

Pfizer_Medicare_NVAF_CAD-PAD_Study Report_11APR2018.pdf (3.08 MB)

# 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 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**

Unknown