The Comparative Safety and Effectiveness of Warfarin and Dabigatran Utilized in the Department of Defense (DoD) Non-Valvular Atrial Fibrillation (NVAF) Patient Population- A Retrospective Database Analysis

First published: 20/05/2015

Last updated: 02/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS9771

Study ID

9772

DARWIN EU® study

No

Study countries

United States

Study description

This study is of a retrospective cohort design with propensity score matching. The primary study objective is to assess the safety and effectiveness of dabigatran compared to warfarin in patients diagnosed with non-valvular atrial fibrillation in the DoD population.

Study status

Finalised

Research institutions and networks

Institutions

PPD Evidera

Sweden

United Kingdom

United States

First published: 20/11/2013

Last updated: 22/09/2025

Institution **Laboratory/Research/Testing facility** **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Evidera Evidera

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/09/2013

Actual: 27/09/2013

Study start date

Planned: 22/01/2014

Actual: 22/01/2014

Data analysis start date

Planned: 04/07/2014

Actual: 23/05/2014

Date of final study report

Planned: 15/06/2015

Actual: 09/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Pharmaceuticals, Inc.

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

1160.183, NCT02043808

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)

Main study objective:

To assess the safety and effectiveness of dabigatran and warfarin in patients diagnosed with non-valvular atrial fibrillation in the DoD population.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PRADAXA

Medicinal product name, other

Warfarin

Study drug International non-proprietary name (INN) or common name

DABIGATRAN ETEXILATE

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

Medical condition to be studied

Atrial fibrillation

Population studied

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)

Estimated number of subjects

28.000

Study design details

Outcomes

stroke (hemorrhagic, ischemic), major bleeding, Ischemic stroke, Hemorrhagic stroke, Major Intracranial bleeding, Major Extracranial bleeding (Major GI bleeding (upper and lower), Major Urogenital bleeding, Major Other bleeding), Transient ischemic attack (TIA), Myocardial infarction (MI),Venous thromboembolism (VTE, deep vein thrombosis DVT or pulmonary embolism PE), Death (all cause)

Data analysis plan

Patients will be followed until OAC discontinuation/switch, disenrollment, death, or study end (whichever occurs first).
Baseline characteristics for the study cohorts will be described and compared for the dabigatran (DE) and warfarin cohorts before and after propensity score matching (PSM).
Inferential statistics will be used to analyze post-match differences between cohorts.
For categorical variables, chi-square tests will be used, and for interval variables, t-tests or, if distribution is not normal, Wilcoxon rank sum test will be conducted.
For the comparison of baseline characteristics before and after PSM, a conventional alpha of 0.05 and two-tailed level of significance will be used unless otherwise specified. To compare the occurrence of primary and secondary outcomes between DE and warfarin cohorts, time to event will be investigated using non-parametric Kaplan-Meier (KM) survival analyses.
Cox proportional hazards models will be implemented if the PSM leaves imbalance.

Documents

Study results

1160-0183_Synopsis.pdf (229.69 KB)

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

No