Sequential Expansion of Comparative Effectiveness of Oral Anticoagulants: A Cohort Study

First published: 05/03/2014

Last updated: 20/10/2026

Study | Finalised

Administrative details

EU PAS number

EUPAS5855

Study ID

31545

DARWIN EU® study

No

Study countries

United States

Study description

This study plans to identify and periodically update cohorts of patients with non-valvular atrial fibrillation at risk for stroke initating oral anticoagulants (dabigatran or warfarin) using electronic claims data from commercial insurance databases and to quantify associations between anticoagulant choice and the occurrence of selected outcomes.

Study status

Finalised

Research institutions and networks

Institutions

Brigham and Women's Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sebastian Schneeweiss

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 06/01/2012

Actual: 06/01/2012

Study start date
Planned: 07/03/2014

Actual: 07/03/2014

Data analysis start date
Planned: 10/03/2014

Actual: 10/03/2014

Date of interim report, if expected
Planned: 30/04/2014

Date of final study report
Planned: 31/03/2017

Actual: 10/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1160-0207_protocol_final-rule_Redacted.pdf (469.26 KB)

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

1160.207

NCT02081807

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Observational cohort study

Main study objective:

Quantify associations between anticoagulant choice (warfarin and dabigatran) and the occurence of selected outcomes in patients with non-valvular atrial fibrillation at risk of stroke

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PRADAXA

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

DABIGATRAN ETEXILATE

WARFARIN

Anatomical Therapeutic Chemical (ATC) code

(B01A) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AA03) warfarin

warfarin

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Patients ≥18 years with a diagnosis of non-valvular atrial fibrillation (NVAF) at risk for stroke (CHA2DS2-VASc score ≥ 1) who initiated treatment either with warfarin, dabigatran, rivaroxaban or apixaban between October 2010 and September 2015.

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

Non-valvular atrial fibrillation patients

Estimated number of subjects

120.000

Study design details

Setting

US MarketScan® Commercial Claims and Encounters database and Medicare Supplement (MarketScan) and OptumClinformatics Research Database (Optum)

Outcomes

StrokeMajor bleeding, Stroke or systemic embolismSystemic embolismIschemic strokeHemorrhagic strokeStroke uncertain classificationTransient ischemic attackMyocardial infarctionVenous thromboembolismDVTPulmonary embolismMajor intracranial bleedingMajor extracranial bleedingMajor GI bleedingMajor upper GI bleedingMajor lower GI bleedingMajor urogenital bleedingMajor other bleeding

Data analysis plan

After identifying initiators of warfarin or dabigatran with an existing diagnosis of non-valvular atrial fibrillation and at risk for stroke in two large US commercial claims databases we will use propensity score methods and time-to-event analyses to estimate the ratio in hazard rates for each of the outcomes of interest.

Summary results

Discussion: The final analyses from this monitoring program remain consistent with what we observed in the interim reports which suggested a reduced risk of both primary outcomes (stroke and major bleeding) with dabigatran relative to warfarin. The primary outcomes were studied across a range of assumptions regarding exposure and within numerous subgroups and these sensitivity analyses were consistent with the results from the primary analyses. Although pooled results in the full cohort are robust, comparative conclusions within some subgroups separately by database remain limited by patient numbers and relatively short follow-up. For the secondary comparisons, analyses suggested a reduced risk of stroke but a similar risk of major bleeding for the comparison of rivaroxaban versus warfarin. For the comparison of apixaban versus warfarin, the analyses suggested a reduced risk for both stroke and major bleeding.

Documents

Study results

1160.207_c25839310-01.pdf (257.54 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 source(s), other

US MarketScan® Commercial Claims and Encounters database and Medicare Supplement (MarketScan), Optum Clinformatics Research Database (Optum)

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